USER'S GUIDE

DEXCOM G4® PLATINUM PROFESSIONAL CONTINUOUS GLUCOSE MONITORING SYSTEM

IMPORTANT CONTACTS AND NUMBERS

Dexcom® Website:	www.dexcom.com
The Transmitter ID:	
The Receiver ID:	
Dexcom Technical Support:	**1.877.339.2664**

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DEXCOM G4 PLATINUM PROFESSIONAL CONTINUOUS GLUCOSE MONITORING SYSTEM

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GLOSSARY

Acoustic Spacer	Small, L-shaped plastic piece to be placed above the receiver speaker to ensure the sound of alerts and alarms is audible.
Alternative Site BG Testing	This is when you take a blood glucose value on the meter using a blood sample from an area on the body other than the fingertip. Do not use alternative site testing to calibrate the receiver.
Applicator	A disposable piece that comes attached to the sensor pod and inserts the sensor under the skin. There is a needle inside the applicator that you remove after you insert the sensor.
Blinded Mode	When the Dexcom G4 PLATINUM Receiver is set to hide sensor glucose readings and glucose trend information. The receiver records glucose information that can be downloaded and reviewed later with the Dexcom STUDIO software.
BG Meter	Blood glucose meter. You can use any commercially available meter for testing blood glucose.
BG Value	Blood glucose value. A blood glucose value taken with the commercially available blood glucose meter.
Calibration	When you enter blood glucose values from a blood glucose meter into the receiver. Calibrations are needed for the receiver to show continuous sensor glucose readings and trend information. (Do not use alternative site testing for calibration).
CGM	Continuous Glucose Monitoring.
Commercially Available	Product that may be sold in the United States.
Default	A setting that is selected automatically, unless you choose another option.

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GLOSSARY (continued from page before)

Dexcom G4 PLATINUM Professional System	The sensor, transmitter, and receiver.
Glucose Data Gaps	Different symbols show on the trend graph instead of a sensor glucose reading to let you know that the receiver cannot provide a reading.
Glucose Trends	Trends let you see the pattern of glucose levels. The trend graph shows where glucose levels have been during the time shown on the screen and where glucose levels are now.
Hypoglycemia	Low blood glucose. Same as "low." The default low alert in the receiver is set to 80 mg/dL. Consult a healthcare professional to determine the appropriate hypoglycemic setting.
Hyperglycemia	High blood glucose. Same as "high." The default high alert in the receiver is set to 200 mg/dL. Consult a healthcare professional to determine the appropriate hyperglycemic setting.
HypoRepeat	Optional receiver alert setting that keeps repeating the fixed low alarm every 5 seconds until the sensor glucose value rises above 55 mg/dL or you confirm it. This profile can be helpful if you want extra awareness for severe lows.
mg/dL	Milligrams per deciliter. The standard unit of measure for sensor glucose readings in the United States.
Obstruction	Something that blocks the path between the transmitter and receiver. There are many types of things that could come between the transmitter and receiver, and Dexcom could not test them all. "Without obstruction" means that we have not tested whether items blocking the transmitter or receiver could affect the transmission range.

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GLOSSARY (continued from page before)

Profiles	Sound pattern and volume level settings for the alerts.
Range	The distance between the receiver and transmitter. Keep the two devices within 20 feet of each other without obstruction to get glucose information on the receiver.
Re-Alert	A re-alert happens after the first alert is not confirmed.
Receiver	The small device that collects glucose information from the sensor/transmitter. The results show on the receiver screen as a sensor glucose reading (mg/dL) and as a trend.
Receiver Shield	Protective shield that is placed over the receiver when used by multiple patients.
Rise and Fall (Rate of Change) Alerts	Alerts based on how fast and how much glucose levels rise/fall.
RF	Radio-frequency transmission used to send glucose information from the transmitter to the receiver.
Safety Lock	The safety lock keeps the needle inside the applicator before you are ready to insert the sensor. It also helps you snap the transmitter out of the sensor pod after the sensor session ends.
Sensor	The Dexcom G4 PLATINUM Professional System part that includes an applicator and wire. The applicator inserts the wire under the skin, and the wire measures glucose levels in tissue fluid.
Sensor Pod	The small plastic base of the sensor attached to the belly that holds the transmitter in place.
Snoozing	The option to delay the alert for a set amount of time. A snooze time can be set for high and low glucose re-alerts.

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GLOSSARY (continued from page before)

Square Seal	Square-shaped tape that is used to seal the USB port of the receiver. Three square seals are provided. Each seal is used once and then discarded when the port is reopened.
Startup Period	The 2-hour period after you tell the receiver you inserted a new sensor. Sensor glucose readings are not provided during this time.
System Reading	A sensor glucose reading shown on the receiver. This reading is in mg/dL units and is updated every 5 minutes.
Transmitter	The Dexcom G4 PLATINUM Professional System part that snaps into the sensor pod and wirelessly sends glucose information to the receiver.
Transmitter ID	A series of numbers and/or letters that you enter into the receiver to let it communicate with the transmitter.
Transmitter Latch	The small, disposable piece that snaps the transmitter into the sensor pod. It is removed after the transmitter is snapped in.
Trend (Rate of Change) Arrows	Arrows on trend graphs that show how fast glucose levels are changing. There are 7 different arrows that show when glucose speed and direction change.
Triangle Seal	Triangle-shaped tape that is used to seal the back of the receiver shield placed over the receiver.

chapter one

DEXCOM G4 PLATINUM PROFESSIONAL CONTINUOUS GLUCOSE MONITORING (CGM) SYSTEM DESCRIPTION

1

CHAPTER 1: DEXCOM G4® PLATINUM PROFESSIONAL CONTINUOUS GLUCOSE MONITORING (CGM) SYSTEM DESCRIPTION

Dexcom G4® PLATINUM Receiver

Dexcom G4 PLATINUM Transmitter

Dexcom G4 PLATINUM Professional Receiver Shield

Dexcom G4 PLATINUM Sensor

1.1 SYSTEM CONTENTS:

- sensor
- transmitter
- receiver
- receiver USB charging/download cable
- AC power adapter - MT21255
- user's guide
- 2 quick start guides (real-time and blinded use)
- site training checklist
- receiver shield pack containing receiver shield, square seals, triangle seal and acoustic spacer
- Dexcom STUDIO™ software CD bundle

Sensors and receiver shields are sold separately. Commercially distributed blood glucose (BG) meter required for use.

PRECAUTION

The Dexcom G4 PLATINUM Sensor, Transmitter, and Receiver are not compatible with the SEVEN®/SEVEN® PLUS Transmitter and Receiver. Different generations will not connect with each other and will not work. Also, make sure to use the correct version of Dexcom STUDIO with your system.

1.2 INTRODUCTION

The system can be used in two modes – real-time and blinded modes. When you use the system in real-time mode, you will see continuous sensor glucose readings updated every 5 minutes for up to 7 days. These readings will help you and your patients notice trends and patterns in their glucose levels. When the system is used in blinded mode, the sensor glucose readings are not displayed to the patient but are recorded every 5 minutes. They can be downloaded and reviewed later using the Dexcom STUDIO software.

The Dexcom G4 PLATINUM Professional System includes the Dexcom G4 PLATINUM Sensor, the Dexcom G4 PLATINUM Transmitter, and the Dexcom G4 PLATINUM Receiver with a receiver shield. The sensor is a disposable unit that you insert under the skin of the abdomen (belly) to continuously monitor glucose levels for up to 7 days. The transmitter is a reusable device that wirelessly sends the sensor's glucose information to the receiver. The receiver is a hand-held device that receives and displays glucose information. When healthcare professionals use one system for multiple patients, the transmitter must be cleaned and disinfected and a new receiver shield must be applied between each patient's use. These disposable receiver shields are components of the Dexcom G4 PLATINUM Professional CGM System that help reduce the

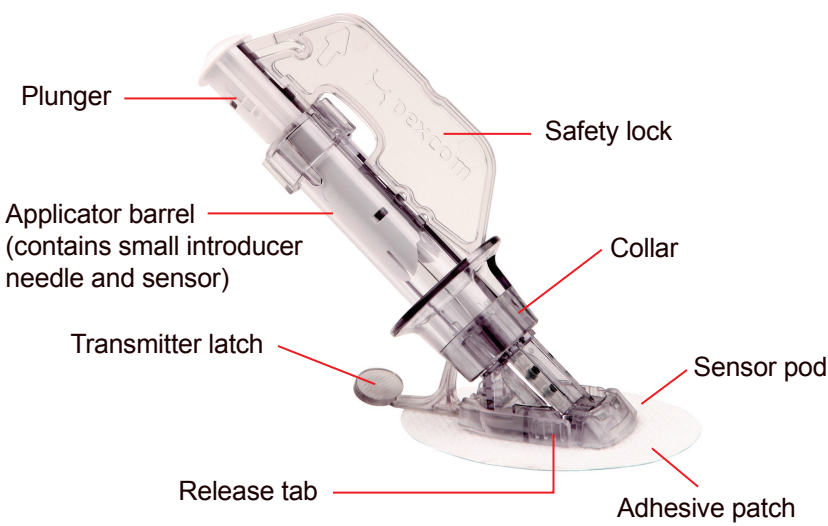
spread of contamination between multiple patient use.

Please read this user's guide closely. It describes how to use the system in detail.

1.3 SENSOR OVERVIEW

The sensor is the piece that comes in a sterile, sealed sensor pouch. The sensor is made up of an applicator, a sensor pod, and a sensor wire. You remove the applicator after insertion. The sensor pod stays on the belly for the entire sensor session, up to 7 days. The pod is made of plastic and an adhesive patch. The sensor wire is thin and flexible, and inserts just under the skin of the belly. It is attached to the sensor pod, and is made of silver and platinum metal with polymer membranes. You discard the sensor at the end of the session.

See Chapter 14 for Product Specifications.



1.4 TRANSMITTER OVERVIEW

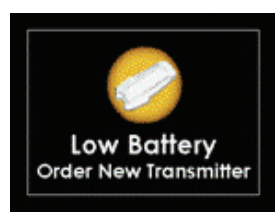
The transmitter is the gray, plastic “chip” that snaps into the sensor pod. The transmitter (including sensor pod) is about 1.5 inches long, 0.9 inches wide and 0.5 inches thick. Once snapped into the sensor pod, the transmitter wirelessly sends the glucose information to the receiver. The transmitter and sensor are water resistant when properly connected. Do not throw away the transmitter. It is reusable. When healthcare professionals use one transmitter for multiple patients, the transmitter must be cleaned and disinfected between each patient’s use.

The transmission range from the transmitter to the receiver is up to 20 feet without obstruction. Wireless communication does not work well through water, so the range is much less if you are in a pool, bathtub or water bed.

The transmitter battery will last at least 6 months. Once you see the transmitter low battery screen, replace the transmitter as soon as possible. The transmitter battery may drain as quickly as one week after this alert appears.

See Chapter 14 for Product Specifications.

Transmitter



Transmitter Low Battery screen

1.5 RECEIVER OVERVIEW

The receiver is the small hand-held device that looks like a cell phone. It is about 4 inches long, 1.8 inches wide and 0.5 inches thick. When used in real-time mode, it shows the sensor glucose readings, trend graph, direction and rate of change arrow. When used in blinded mode, it records, but does not display, sensor glucose readings throughout the sensor session. Regardless of the mode used, the receiver alerts the patient to any errors in the system, such as low battery. When healthcare professionals use one receiver for multiple patients, the receiver shield must be replaced between each patient's use. The shield is a thin, stretchy plastic that covers the receiver.

Receiver shield

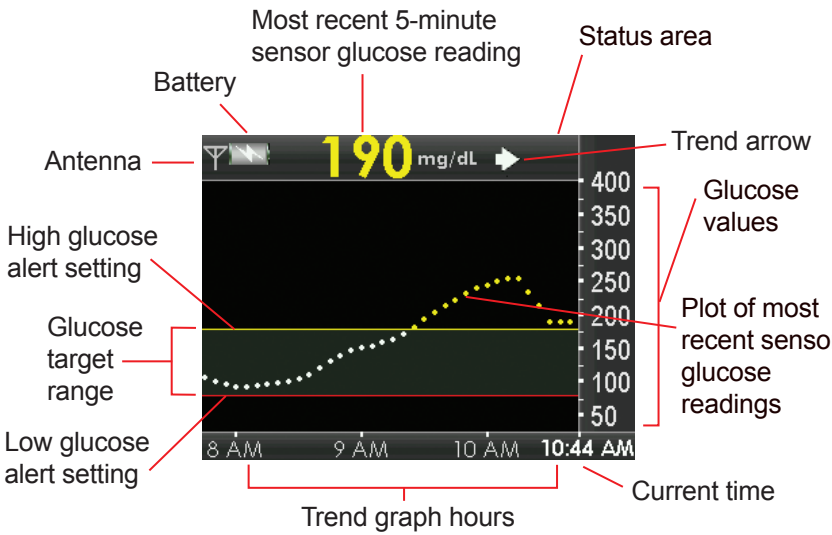
Do not spill fluids on the receiver or drop the receiver into fluids. Keep the micro USB port door open, and keep the square seal on the receiver shield over the USB port.

NOTE: The receiver will store each patient's data in its memory. For multiple patient use, it is important that you erase the receiver data memory after each patient use. This will ensure patient privacy with subsequent users. See Chapter 10 for instructions on erasing patient data from the receiver.

NOTE: In the Dexcom STUDIO software, select the "Prompt to reset receiver after every download" option under the Options - Healthcare Professional setting. This feature will remind the healthcare professional to erase the receiver data after each use.

1

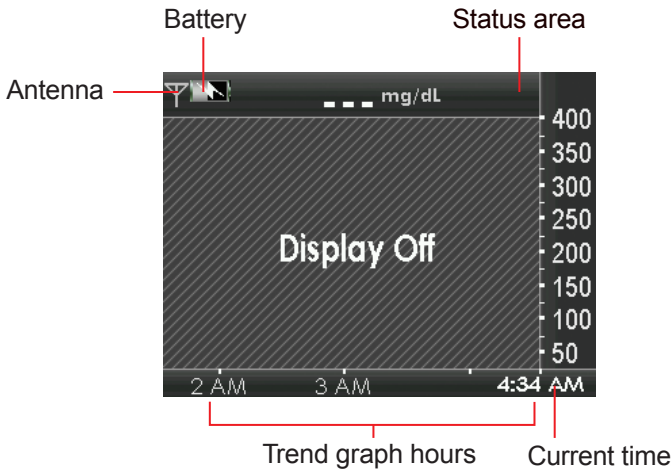
Real-Time Receiver Mode:



EXAMPLE: 3-Hour Trend Graph Screen

When used in real-time mode, the trend graph screen on the receiver shows the sensor glucose readings, trend graph, direction and rate of change arrow.

Blinded Receiver Mode:



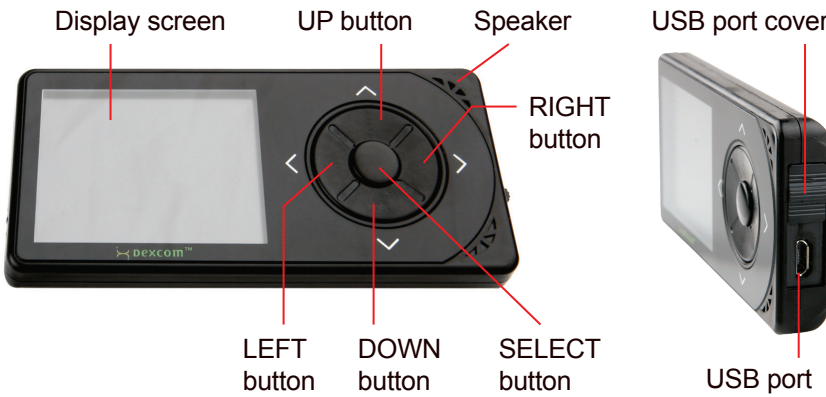
When used in blinded mode, no sensor glucose readings are displayed to the patient, but the sensor readings are recorded every 5 minutes and can be downloaded and reviewed later using the Dexcom STUDIO software.

There are five receiver buttons to move you through the screens. When in real-time mode, the trend graph screens show sensor glucose readings, trend graphs and trend arrows. The receiver menu screens let you change the receiver settings.

The receiver and transmitter wirelessly pair together to communicate securely and only with each other.

You will need a commercially available blood glucose meter to use with the system.

See Section 14 for Product Specifications.

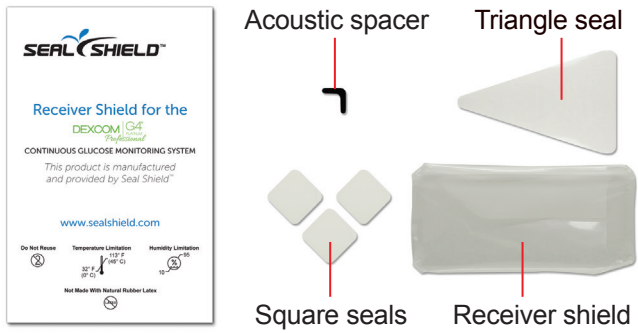


Receiver buttons:

- Press the **UP** and **DOWN** buttons to scroll through trend screens, highlight menu items, or set values.
- Press the **SELECT** button to turn the receiver on or select the highlighted option.
- Press the **LEFT** button to go back to the last item or screen.
- Press the **RIGHT** button to highlight the next item.

1.6 RECEIVER SHIELD OVERVIEW

The Dexcom G4 PLATINUM Professional System requires the use of the receiver shield and its components to help protect the receiver from contamination. The receiver shield pack includes the receiver shield, 3 square seals, 1 triangle seal and 1 acoustic spacer.



Receiver shield pack

The receiver shield and components are disposable and must be replaced with each individual patient's use. The receiver shield and seals are used to help protect the receiver from contamination. The acoustic spacer is used to ensure the alert and alarm sounds are still audible when the receiver shield is over the receiver.

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chapter two

INDICATIONS FOR USE AND SAFETY STATEMENT

2

CHAPTER 2: INDICATIONS FOR USE AND SAFETY STATEMENT

2.1 INDICATIONS FOR USE

The Dexcom G4 PLATINUM Professional Continuous Glucose Monitoring System is a glucose monitoring device indicated for detecting trends and tracking patterns in persons **(age 18 and older)** with diabetes. The system is intended for multiple patient use and requires purchase by a healthcare provider. The system is not intended for use in a hospital setting.

The Dexcom G4 PLATINUM Professional System is indicated for use as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices.

The Dexcom G4 PLATINUM Professional System aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of the Dexcom G4 PLATINUM Professional System results should be based on the trends and patterns seen with several sequential readings over time.

2.2 IMPORTANT USER INFORMATION

Please review your product instructions before using your continuous glucose monitoring system. Indications, contraindications, warnings, precautions, cautions, and other important user information can be found in your product instructions. Discuss with your healthcare professional how you should use your sensor trend information to help

manage your diabetes. Your product instructions contain important information on troubleshooting your system and on the performance characteristics of the device.

2.3 CONTRAINDICATIONS

- Remove the Dexcom G4 PLATINUM Sensor, Transmitter, and Receiver before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. The device is MR Unsafe. Do not bring any portion of the device into the MR environment. The Dexcom G4 PLATINUM Professional System has not been tested during MRI or CT scans or with diathermy treatment. The magnetic fields and heat could damage the device so that it might not display sensor glucose readings or provide alerts, and you might miss a low or high blood glucose value.
- Taking medications with acetaminophen (such as Tylenol®) while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.

2.4 WARNINGS

- Thoroughly review the training materials included with your CGM system before using the Dexcom G4 PLATINUM Professional CGM System. Incorrect use might lead to you misunderstanding the information provided by your system, or might affect system performance, and you might miss a low or high blood glucose value.

- Do not use the Dexcom G4 PLATINUM Professional System for treatment decisions, such as how much insulin you should take. The Dexcom G4 PLATINUM Professional System does not replace a blood glucose meter. Always use the values from your blood glucose meter for treatment decisions. Blood glucose values may differ from sensor glucose readings. Using the sensor glucose readings for treatment decisions could lead to low or high blood glucose value.
- Do not ignore symptoms of high and low glucose. If your sensor glucose readings do not match your symptoms, measure your blood glucose with a blood glucose meter even if your sensor is not reading in the high or low range, so you do not miss a low or high blood glucose value.
- Calibrate at least once every 12 hours. Calibrating less often than every 12 hours might cause sensor glucose readings to be inaccurate, and you might miss a low or high blood glucose value.
- Users need to adhere to Standard Precautions when handling or using this device. All parts of the system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. For more information, refer to “Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007,” http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html.
- The transmitter should be cleaned and disinfected after use on each patient. This system may only be used for testing multiple patients when Standard Precautions and the

manufacturer's cleaning and disinfection procedures are followed.

- Replace the receiver shield and acoustic spacer when transferring the receiver to a new patient. Wear gloves when handling the receiver. Handling the receiver without a shield or with a damaged shield could lead to contamination, which could cause infection.
- Sensors may fracture on rare occasions. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the insertion site. If you experience a broken sensor, please report this to our Technical Support department at **1.877.339.2664 or 1.858.200.0200.**
- The Dexcom G4 PLATINUM Professional System **is not approved for use** in children or adolescents, pregnant women or persons on dialysis.
- It is not known how different conditions or medications common to the critically ill population may affect the performance of the system. Therefore, the use of this system in the critically ill population is not recommended.
- Sensor placement and insertion **is not approved** for sites other than the belly (abdomen).
- Do not expect alerts from the Dexcom G4 PLATINUM Professional System until after the 2-hour startup. You will NOT get any sensor glucose readings or alerts until after the 2-hour startup ends AND you complete the startup calibration. During this time you might miss severe hypoglycemia (low blood glucose) or hyperglycemia (high

blood glucose) events.

- If your transmitter or receiver case is damaged/cracked, do not use it. This could create an electrical safety hazard or malfunction, which might cause electrical shocks.
- Store the sensor at temperatures between 36° F - 77° F for the length of the sensor's shelf life. You may store the sensor in the refrigerator if it is within this temperature range. The sensor should not be stored in a freezer. Storing the sensor improperly might cause the sensor glucose readings to be inaccurate, and you might miss a low or high blood glucose value.
- Low/high glucose alerts and the 55 mg/dL low glucose alarm are all disabled when using the Dexcom G4 PLATINUM Professional System in blinded mode and will not alert you when the glucose is low or high. Check blood glucose meter if there are any signs or symptoms of low or high glucose.

2.5 PRECAUTIONS

- Before opening the sensor package, wash your hands with soap and water, and let them dry. You may contaminate the insertion site and suffer an infection if you have dirty hands while inserting the sensor.
- Before inserting the sensor, clean the skin with a topical antimicrobial solution, such as isopropyl alcohol, and allow to dry. This may help prevent infection. Do not insert the sensor until the cleaned area is dry so the sensor adhesive will stick better.
- Change the site where you place the sensor with each

insertion, if the system is used multiple times. Using the same site too often might not allow the skin to heal, and might cause scarring or skin irritation.

- Avoid inserting the sensor in areas that are likely to be bumped, pushed or compressed or areas of skin with scarring, tattoos, or irritation as these are not ideal sites to measure glucose. Insertion in those areas might affect sensor performance, and you might miss a low or high blood glucose value.
- Avoid injecting insulin or placing an insulin pump infusion set within 3 inches of the sensor. The insulin might affect sensor performance, and you might miss a low or high blood glucose value.
- Do not use the sensor if its sterile package has been damaged or opened. Using an unsterile sensor might cause infection.
- To calibrate the system, enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose measurement. Entering incorrect blood glucose values or blood glucose values from more than 5 minutes before entry might affect sensor performance, and you might miss a low or high blood glucose value.
- Do not calibrate if your blood glucose is changing at a significant rate, typically more than 2 mg/dL per minute. Do not calibrate when your receiver screen is showing the rising single arrow or double arrow, which indicates that your blood glucose is rising 2-3 mg/dL/min or more than 3 mg/dL/min. Also, do not calibrate when your receiver

screen is showing the falling single arrow or double arrow, which indicates that your blood glucose is falling 2-3 mg/dL/min or more than 3 mg/dL/min. Calibrating during significant rise or fall of blood glucose may affect accuracy of sensor glucose readings.

- The system accuracy may be affected when your glucose is changing at a significant rate (e.g., 2-3 mg/dL/min or more than 3 mg/dL each minute), such as during exercise or after a meal. Since the system will not display your glucose rate of change in blinded mode, avoid calibrating after a meal or exercise.
- The transmission range from the transmitter to the receiver is up to 20 feet without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, or on a water bed, etc. Types of obstruction differ and have not been tested. If your transmitter and receiver are farther than 20 feet apart or are separated by an obstruction, they might not communicate or the communication distance may be shorter and you might miss a low or high blood glucose value.
- Do not use alternative blood glucose site testing (blood from your palm or forearm, etc.) for calibration. Alternative site blood glucose values may be different than those taken from a fingerstick blood glucose value and may not represent the timeliest blood glucose value. Use a blood glucose value taken only from a fingerstick for calibration. Alternative site blood glucose values might affect sensor performance, and you might miss a low or high blood glucose value.

- Do not discard your transmitter. It is reusable. The same transmitter is used for each session until you have reached the end of the transmitter battery life. When healthcare professionals use one transmitter for multiple patients, the transmitter must be returned to the healthcare professional.
- The Dexcom G4 PLATINUM Sensor, Transmitter, and Receiver are not compatible with the SEVEN/SEVEN PLUS Transmitter and Receiver. Different generations will not connect with each other and will not work. Also make sure to use the correct version of Dexcom STUDIO with your system.
- If all 3 square seals have been used before the end of the session, return the receiver to the healthcare professional office. Do not charge the receiver if you cannot seal it. Unsealed receivers could spread contamination.
- Do not puncture the receiver shield for any reason. Punctured shields could spread contamination.
- Return the receiver to the healthcare professional if the acoustic spacer moves away from the upper right corner. The entire receiver shield must be discarded and replaced. The spacer allows the receiver speaker to work properly when the shield is in place. If the spacer moves and the receiver speaker volume is low, you might miss alerts or alarms.
- Inspect the receiver shield, seals and spacer for tears or other damage or defects before you place the components on the receiver. Do not use any parts of the receiver shield pack that are damaged or defective. If the receiver shield, seals and spacer are torn, damaged or otherwise defective

after giving to the patient, the patient should return the receiver to the healthcare professional for a replacement. The damaged or defective receiver shield should not be taken off by the patient. If a defect or malfunction is suspected, the healthcare professional should retain the shield and contact Dexcom® Technical Support. The shield helps protect the user and healthcare professionals from contamination and allows the receiver to function properly.

2.6 CAUTION

U.S. (Federal) law restricts the sale of the Dexcom G4 PLATINUM Professional System to sale by or on order of a physician.

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chapter three

RISKS AND BENEFITS

3

CHAPTER 3: RISKS AND BENEFITS

3.1 RISKS

There are some known risks with using real-time or blinded CGM.

You will not get sensor glucose alerts when the alert function is turned off, your transmitter and receiver are out of range, or when your receiver is not showing sensor glucose readings. You might not notice alerts if you are unable to hear them or feel the vibration. Sometimes your sensor glucose reading may be slightly different than your blood glucose meter. For example, your blood glucose meter may show a blood glucose value of 78 mg/dL, but your sensor glucose reading may show as 82 mg/dL. If your low alert is set at 80 mg/dL, your system will not alert for a low glucose at this time because 82 mg/dL is still above your low alert setting. In most cases, the sensor glucose readings will move in the right direction and will alert you of a high or low shortly after. If you do not get an alert for any reason, and you do not take frequent blood glucose measurements with your blood glucose meter, you might not be aware of low or high blood glucose levels. If this happens, and your blood glucose levels are very high or low, there is a remote chance you might need medical help. There is a risk of disease transmission when the device is used on multiple patients.

When the CGM system is used in blinded mode, the sensor glucose readings are not displayed, only recorded for review when downloaded later by the Dexcom STUDIO software. Using the system in blinded mode might cause you to expect glucose alerts, but you will not receive high

or low glucose alerts in blinded mode since these alerts are deactivated. Taking frequent blood glucose measurements is necessary to be aware of low or high blood glucose levels.

Inserting the sensor and wearing the adhesive patch might cause infection, bleeding, pain or skin irritations (redness, swelling, bruising, itching, scarring or skin discoloration). There is a low chance of this happening. In the clinical study for the Dexcom G4 PLATINUM System (which used the same sensor as the Dexcom G4 PLATINUM Professional System), only slight redness and swelling occurred in a few patients. If any of these events happen, you might feel discomfort in the area the sensor is inserted.

There is a remote chance that a sensor fragment could remain under your skin if the sensor breaks while you are wearing it. This did not happen in the clinical study for the Dexcom G4 PLATINUM System. If you think a sensor has broken under your skin, contact your healthcare professional and call Dexcom's Technical Support. Sensor breakage may cause some anxiety, but it is not a significant medical risk.

3.2 BENEFITS

Real-time CGM provides benefits beyond the information you get from a blood glucose meter. It provides glucose readings every five minutes for up to seven days to help you detect trends and patterns in your glucose levels. This trend information can help you see where your glucose is now as well as where your glucose may be heading and how fast you may be getting there. Understanding your glucose trends and patterns may help you take action to help avoid high or low glucose values by working with your healthcare

professional to adjust your diabetes management therapy or techniques.

Alerts and the low alarm tell you when your glucose is outside of your target glucose range and may help you avoid low and high blood sugar. Rise and fall glucose alerts can also provide benefit by alerting you when your glucose is rapidly going down or up. This way you can be alerted to this information before you are too high or too low and take action to avoid it. Real-time CGM can help increase time in your target glucose range without increasing your time in the low or high glucose range.[1]

Real-time CGM can help improve diabetes control (lower A1c values, reducing glycemic variability and time spent in low and high blood glucose ranges)[1, 2, 3] which can help reduce diabetes related complications.[4, 5] These benefits can be seen especially with using real-time CGM at least 6 days per week[2] and can be sustained over time.[6] In some cases, patients perceived an increase in their quality of life and peace of mind when using real-time CGM as well as reporting a high satisfaction with CGM.[7]

Blinded CGM also provides benefit to both the patient and healthcare professionals. Using blinded CGM allows for the uninterrupted glucose patterns and trends of a patient's daily schedule be documented so glucose patterns and trends can be identified and changes to their diabetes management can be made to help avoid glucose excursions. Blinded CGM can also allow for assessment of the true diurnal glucose patterns as it relates to basal management adjustment and lifestyle choices of diet and exercise.

3

[1] Garg S, Zisser H, Schwartz S, Bailey T, Kaplan R, Ellis S, Jovanovic L. Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor: a randomized controlled trial. *Diabetes Care*. 2006; 29:44-50.

[2] JDRF CGM Study Group. Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes. *NEJM* 2008;359:1464-76.

[3] Battelino. Effect of continuous glucose monitoring of hypoglycemia in type 1 diabetes. *Diabetes Care* 2011; 34(4): 795-800.

[4] The Diabetes Control and Complications Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications of insulin-dependent diabetes mellitus. *N Eng J Med*. 1993; 329:997-1036.

[5] Ohkubo Y, Kishikawa H, Araki E, et al. Intensive insulin therapy prevents progression of diabetic microvascular complications in Japanese patients with non-insulin dependent diabetes mellitus: a randomized prospective 6-year study. *Diabetes Res Clin Pract.* 1995; 28:103-117.

[6] JDRF CGM Study Group. Sustained Benefit of Continuous Glucose Monitoring on A1c, Glucose Profiles, and Hypoglycemia in Adults With Type 1 Diabetes, *Diabetes Care* 2009; 32: 2047-2049.

[7] JDRF CGM Study Group. Quality-of-Life Measures in Children and Adults With Type 1 Diabetes. *Diabetes Care* 2010; 33: 2175-2177.

chapter four

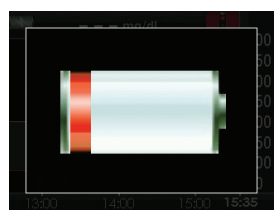
CHARGING THE RECEIVER AND THE RECEIVER MAIN MENU

4

CHAPTER 4: CHARGING THE RECEIVER AND THE RECEIVER MAIN MENU

4.1 CHARGING THE RECEIVER BATTERY

The receiver battery is rechargeable and will last about 3 days with normal use before you need to charge it. The battery life depends on how often you press the receiver buttons or get alerts. The receiver will tell you when the battery charge is low.



Low battery prompt

Charge the receiver battery using one of these options:

- an AC power outlet
- a personal computer with Windows® operating system (to charge the receiver from the PC, Dexcom STUDIO must be installed. For system requirements and more information, see the Dexcom website (www.dexcom.com) or the Dexcom STUDIO Software User's Guide.)

Only use the Dexcom battery charger provided in the receiver kit. Do not use any other battery charger.

Charge only from a USB port on the computer or the AC power adapter. Do not use an external USB hub. An external USB hub may not provide enough power to charge the receiver.

Fully charging an empty battery takes about 3 hours with the wall charger and about 5 hours with a computer. The battery does not need to be drained to charge fully.

You may use the receiver while it is charging with an AC power outlet or PC.

Charge the receiver battery before each sensor insertion. Periodically check the battery level to make sure it has enough charge.

If the battery drains, it will keep the time and date for 3 days without being charged. After 3 days, the receiver will prompt you to reset the time and date (see Chapter 5, Section 5.2, The Settings Menu).

When the receiver is used in a healthcare facility, charging must take place away from the patient.

When the receiver is used for multiple patients, charging should take place before the patient is given the system so only a recharge would be necessary during the 7- day sensor session.

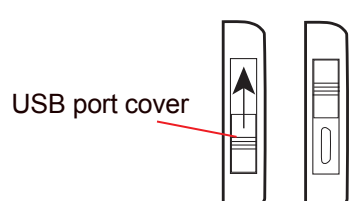
WARNING

It is not known how different conditions or medications common to the critically ill population may affect the performance of the system. Therefore, the use of this system in the critically ill population is not recommended.

4.1.1 CHARGING THE RECEIVER BATTERY FROM AN AC POWER OUTLET

To recharge the battery during the 7-day sensor session:

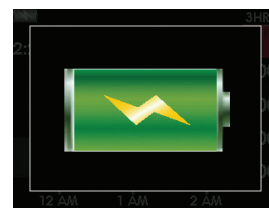
1. Carefully peel back the square seal that is over the USB port.
2. Plug the included USB cable into the AC power adapter.
3. Plug the AC power adapter into an AC power outlet.
4. Make sure the USB door is open so you can reach the port easily. If it is closed, press down firmly with a thumb when sliding open the USB port cover.



5. Plug the micro USB end of the cable into the receiver USB port.

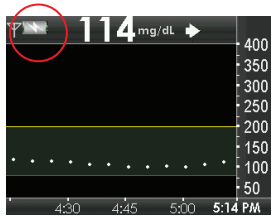
Keep the USB port cover on the receiver open whenever the USB cable is not attached. The receiver shield works with the port open so you can access the USB port easily as needed.

6. The battery charging screen will show on the receiver.



Battery charging screen

7. After a few seconds the trend graph will show with the battery charging symbol ( ) in the upper left corner.



Battery charging symbol in upper left corner of trend graph in real-time mode

Battery charging symbol in upper left corner of trend graph in blinded mode

4.1.2 CHARGING THE RECEIVER BATTERY FROM A WINDOWS COMPATIBLE COMPUTER

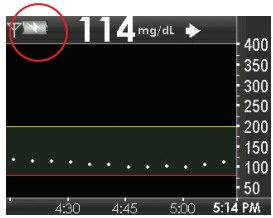
You must install the Dexcom STUDIO software to charge the receiver from a computer. Please see the Dexcom STUDIO Installation Card for driver installation instructions. This charging option should be used by the healthcare professional only.

1. Carefully peel back the square seal that is over the USB port.

2. Plug the included USB cable into the computer.
3. Plug the other end of the USB cable into the receiver.
4. The battery charging screen shows on the receiver.

Battery charging screen

5. After a few seconds, the trend graph screen will show the battery charging symbol in the upper left corner.



Battery charging symbol in upper left corner of trend graph in real-time mode

Battery charging symbol in upper left corner of trend graph in blinded mode

4.1.3 KNOWING THE RECEIVER IS CHARGED

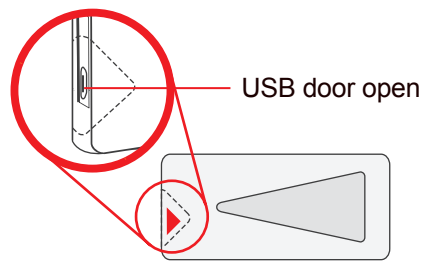
As the battery charges, the battery charging symbol fills in. When the battery is fully charged, the battery charging symbol is completely shaded.

Start Fully Charged

Battery charging symbol fills in as battery charges

After the receiver is fully charged:

1. Disconnect the cable and power adapter.
2. Do not move the USB port cover; leave it open.
3. Carefully remove the square seal over the USB port.
4. Place a new square seal over the receiver USB port by peeling the seal from the tape backing and placing the seal over the USB port in a diagonal shape. This reseals the port.



Square seal on receiver shield

5. Press firmly on the square seal to make sure it is sealed securely.

PRECAUTION

If all 3 square seals have been used before the end of the session, return the receiver to the healthcare professional office. Do not charge the receiver if you cannot seal it. Unsealed receivers could spread contamination.

4.2 RECEIVER MENU OPTIONS

The receiver's Main Menu lets you scroll through important menu options. This table explains the purpose of each option. These menu options can be seen in both real-time and blinded modes. More information on Main Menu options can be found in the chapters listed:

Receiver Main Menu Options

Menu	Purpose	User's Guide Reference
Trend Graph	To show the trend graphs. • The 3-hour trend graph is the default screen whenever you turn on the receiver.	Chapter 8
Start Sensor	To start a new sensor session. • This option only shows if you have entered a transmitter ID and you are not in the middle of a sensor session	Chapter 6
Enter BG	To enter blood glucose values for calibration.	Chapter 7
Profiles	Profiles allow you to customize the sound and volume of alerts and alarm.	Chapter 9
Events	To enter personal information about meals, insulin, exercise, and health status.	Chapter 10
Alerts, High/Low	To change the settings for high and low alerts. High and low alerts and alarm are not activated in blinded mode.	Chapter 9
Settings	To change the time, date and transmitter ID; to look up the Dexcom G4 PLATINUM Professional System hardware and software version numbers; to view transmitter battery status, last calibration value and sensor insertion time.	Chapter 5
Shutdown	To temporarily turn off all communication between the transmitter and receiver during a sensor session. You will not get sensor glucose readings, and it will not extend the life of the sensor.	Chapter 6
Stop Sensor	To end a sensor session early. • This option only shows when you are in the middle of a sensor session. You will not get sensor glucose readings, and you must dispose of the sensor if you stop the session.	Chapter 13

See Chapter 18, Appendix I, Receiver Alerts, Alarm and Prompts, for a list of screens that may show on the receiver.

chapter five

DEXCOM G4 PLATINUM PROFESSIONAL SYSTEM INITIAL SETUP

5

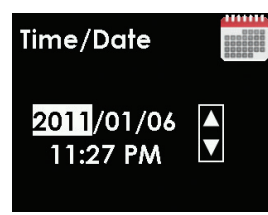
CHAPTER 5: DEXCOM G4 PLATINUM PROFESSIONAL SYSTEM INITIAL SETUP

This chapter helps you when you first set up the Continuous Glucose Monitoring system. Read this chapter before you start.

5.1 SETTING UP THE RECEIVER AND PAIRING WITH THE TRANSMITTER

The Setup Wizard guides you through setup the first time you turn on the receiver. These set up tasks are only needed to be done when a new receiver is used for the first time.

1. Remove the transmitter from its packaging. Wait 10 minutes for the transmitter to turn on before setting up the receiver.
2. Make sure the receiver is fully charged (see Chapter 4, Section 4.1, Charging The Receiver Battery).
3. Press the **SELECT** button on the receiver to turn it on. The Setup Wizard will guide you to enter the following setup information:
   a. Set the time and date. The date format is YYYY/MM/DD.
      (1) Press the **UP** or **DOWN** button to enter the current date and time.
      (2) Press the **RIGHT** or **SELECT** button to move to the next section.
      (3) Press the **SELECT** button to confirm time and date.



Time/Date setting screen

   b. Enter the transmitter ID.

(1) Press the **UP** or **DOWN** button to enter the transmitter ID.

(2) Press the **RIGHT** or **SELECT** button to move to the next space.

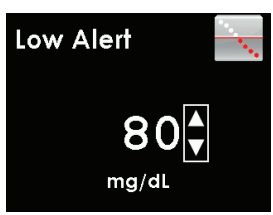
(3) Press the **SELECT** button after you enter the last number or letter to confirm the transmitter ID.

Transmitter ID setting screen

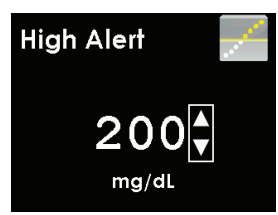
The transmitter ID is a unique code with 5 numbers and/or letters found in the following locations:

- On the transmitter box label
- On the bottom of the transmitter

c. Set the low and high glucose alert values appropriate for each individual patient. The low and high glucose alerts are pre-set to 80 mg/dL and 200 mg/dL but can be changed.



Low Alert setting screen



High Alert setting screen

NOTE: Even though alerts and alarm for low or high glucose levels are inactive in blinded mode, you must set the low and high alert levels as part of the Setup Wizard process in order to proceed.

WARNING

Low/high glucose alerts and the 55 mg/dL low glucose alarm are all disabled when using the Dexcom G4 PLATINUM Professional System in blinded mode and will not alert you when the glucose is low or high. Check blood glucose meter if there are any signs or symptoms of low or high glucose.

(1) Press the **UP** or **DOWN** button to select the alert level. The low alert can be changed in steps of 5 mg/dL, and the high alert can be changed in steps of 10 mg/dL.

(2) Press the **SELECT** button to confirm the alert level.

- You can also change the alert levels in the Alerts menu.
- The unit of measurement (mg/dL) is not adjustable.
- If you need to change the time, date or transmitter ID after you complete the Setup Wizard see Section 5.2, The Settings Menu.

The Setup Wizard is now complete. To start using the Dexcom G4 PLATINUM Professional CGM System you must insert a sensor (see Chapter 6, Inserting a Sensor and Starting a Sensor Session).

5.2 THE SETTINGS MENU

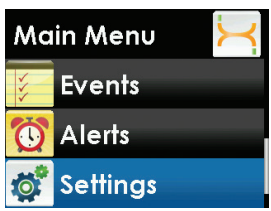
The Settings menu lets you change the time, date or transmitter ID. The Setup Wizard only works the first time you turn on the receiver, but you can always use the Settings menu to make changes to the transmitter ID, time and date, etc.

5.2.1 GETTING TO THE SETTINGS MENU

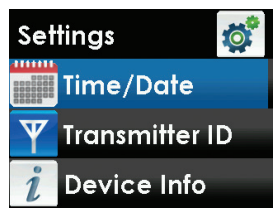
1. Press the **SELECT** button to turn on the receiver. The 3-hour trend

graph shows.

2. Press the **SELECT** button to see the Main Menu.
3. From the Main Menu, press the **UP** or **DOWN** button to scroll to "Settings" and press the **SELECT** button. The Settings menu shows:



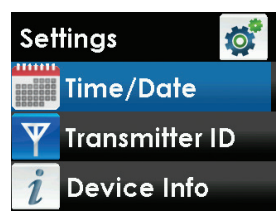
Main Menu,
Settings highlighted



Settings menu

5.2.2 SETTING THE RECEIVER TIME AND DATE

1. From the Settings menu, press the **UP** or **DOWN** button to scroll to "Time/Date," and press the **SELECT** button.

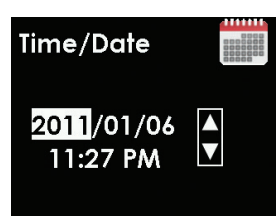


Settings menu,
Time/Date highlighted

2. Press the **RIGHT** button to highlight each value in the date and time.
3. Press the **UP** or **DOWN** button to make any changes.
4. Press the **RIGHT** button to move to the next value.

The date format is YYYY/MM/DD.

5. Press the **SELECT** button after choosing



Time/Date setting screen,
year highlighted

"AM" or "PM." You will return to the Settings menu.

You might need to reset the receiver's time and date if the rechargeable battery drains. If this happens, the receiver will alert you and automatically take you to the Time/Date setting screen.

5.2.3 ENTERING THE TRANSMITTER ID

Any time you switch to a new transmitter and/or receiver you must enter the transmitter ID into the receiver. The transmitter ID is a series of 5 numbers and/or letters that can be found in the following locations:

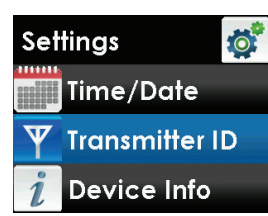
- On the transmitter box label
- On the bottom of the transmitter

If you cannot find the transmitter ID, please contact Dexcom Technical Support (see Chapter 15, User Assistance).

You can only set the transmitter ID when you are not in a sensor session. During a sensor session, "Transmitter ID" will not be an option on the Settings menu.

To enter the transmitter ID follow these steps:

1. From the Settings menu, press the **UP** or **DOWN** button to scroll to "Transmitter ID" and press the **SELECT** button.



Settings menu,
Transmitter ID highlighted

2. Start with the first number or letter (do not enter "SN"):

a. Press the **UP** or **DOWN** button to show the correct number or letter.

b. Press the **RIGHT** or **SELECT** button to move to the next value and repeat step a.

c. Continue repeating steps a and b to enter the whole transmitter ID.

d. Press the **SELECT** button after you enter the last number or letter. You will return to the Settings menu.

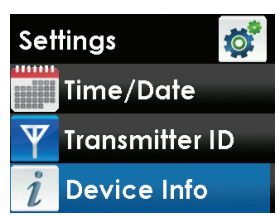
Transmitter ID setting screen, first digit highlighted

NOTE: The "Transmitter ID" menu option is marked with an antenna symbol as a graphical flag; it does not tell you whether the transmitter and receiver are communicating. The "Transmitter ID" menu option only shows when you are not in a sensor session. See Section 5.4 for the antenna symbol that shows whether the transmitter and receiver are communicating.

5.3 CHECKING INFORMATION ABOUT THE DEXCOM G4 PLATINUM PROFESSIONAL SYSTEM

You can check the receiver for information about the CGM system at any time.

1. From the Settings menu, press the **UP** or **DOWN** button to scroll to "Device Info."
2. Press the **SELECT** button. Information about the sensor session and system will show.



Settings menu, Device Info highlighted

3. Scroll down to see all of the Device Info:
    - Insertion Time
    - Last Calibration
    - Transmitter Battery

- Transmitter ID
- Serial Number
- Part Number
- Part Revision
- Software Number
- Software Revision

Device Info screen

4. Press the **LEFT** button to return to the Settings menu.

When healthcare professionals use more than one system in their practice, remember to check that the correct Transmitter ID is entered into the receiver.

5.4 TRANSMITTER AND RECEIVER COMMUNICATION

When you are in a sensor session, you can check that the receiver and transmitter are communicating.

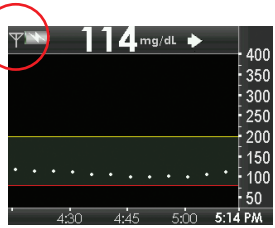
CONTRAINDICATION

MR Remove the Dexcom G4 PLATINUM Sensor, Transmitter, and Receiver before Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or diathermy treatment. The device is MR Unsafe. Do not bring any portion of the device into the MR environment. The Dexcom G4 PLATINUM Professional System has not been tested during MRI or CT scans or with diathermy treatment. The magnetic fields and heat could damage the device so that it might not display sensor glucose readings or provide alerts, and you might miss a low or high blood glucose value.

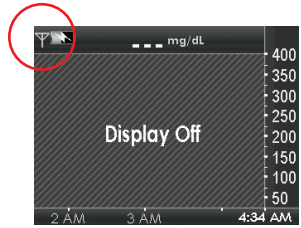
PRECAUTION

The transmission range from the transmitter to the receiver is up to 20 feet without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, or on a water bed, etc. Types of obstruction differ and have not been tested. If your transmitter and receiver are farther than 20 feet apart or are separated by an obstruction, they might not communicate or the communication distance may be shorter and you might miss a low or high blood glucose value.

Press the **SELECT**, **LEFT** or **RIGHT** button to see the trend graph. This antenna symbol shows that the transmitter and receiver are communicating.

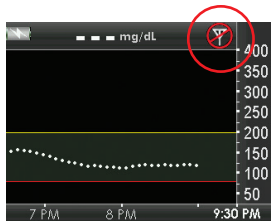


Antenna symbol appears in upper left of trend graph in real-time mode

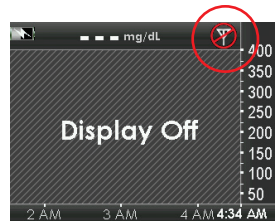


Antenna symbol appears in upper left of trend graph in blinded mode

This out of range symbol shows the transmitter and receiver are not communicating. See Chapter 13 for troubleshooting instructions if the out of range symbol appears.



Out of range symbol appears in upper right of trend graph in real-time mode



Out of range symbol appears in upper right of trend graph in blinded mode

5.5 USING THE RECEIVER SHIELD AND PREPARING THE RECEIVER FOR MULTIPLE PATIENT USE

PRECAUTIONS

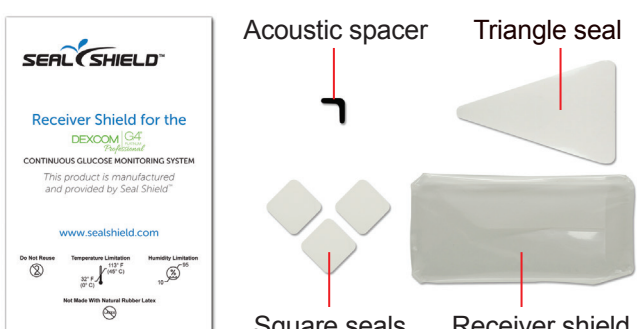
- If all 3 square seals have been used before the end of the session, return the receiver to the healthcare professional office. Do not charge the receiver if you cannot seal it. Unsealed receivers could spread contamination.
- Do not puncture the receiver shield for any reason. Punctured shields could spread contamination.
- Return the receiver to the healthcare professional if the acoustic spacer moves away from the upper right corner. The entire receiver shield must be discarded and replaced. The spacer allows the receiver speaker to work properly when the shield is in place. If the spacer moves and the receiver speaker volume is low, you might miss alerts or alarms.

5

PRECAUTION

Inspect the receiver shield, seals and spacer for tears or other damage or defects before you place the components on the receiver. Do not use any parts of the receiver shield pack that are damaged or defective. If the receiver shield, seals and spacer are torn, damaged or otherwise defective after giving to the patient, the patient should return the receiver to the healthcare professional for a replacement. The damaged or defective receiver shield should not be taken off by the patient. If a defect or malfunction is suspected, the healthcare professional should retain the shield and contact Dexcom Technical Support. The shield helps protect the user and healthcare professionals from contamination and allows the receiver to function properly.

The Dexcom G4 PLATINUM Receiver is protected by a receiver shield when used with multiple patients.



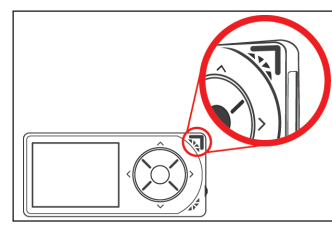
Receiver shield pack

The receiver shield pack includes:

- Receiver shield
- 1 triangle seal (tape to cover the slot in the back of the receiver shield)
- 3 square seals (tape to cover the USB port)
- 1 acoustic spacer to ensure proper volume from the receiver

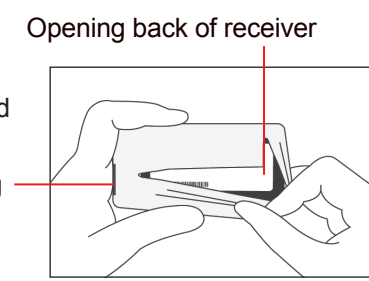
Before inserting the sensor and giving the receiver to the patient for their 7-day session, you need to place the acoustic spacer, receiver shield, and seals:

1. Wash hands and put on sterile gloves. Peel acoustic spacer from paper backing and secure on upper speaker edge.



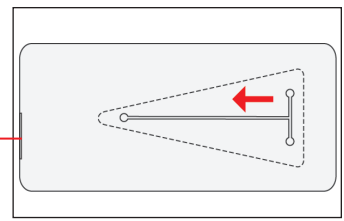
Acoustic spacer in upper right of receiver

2. Note location of USB opening on receiver shield. Stretch receiver shield over receiver.

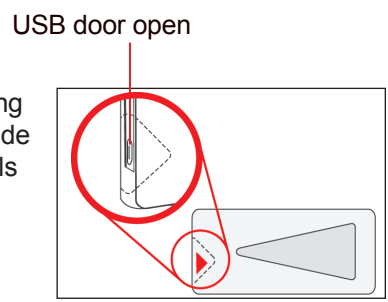


Stretch receiver shield over receiver

3. Peel triangle seal from paper backing and secure seal over opening on back of receiver.



Triangle seal over shield opening



4. Peel 1 square seal from paper backing and secure seal over USB door on side of receiver. Save additional USB seals for recharging.

Square seal over USB port

NOTE: The receiver shield is not waterproof.

Be sure to instruct the patient on how to properly recharge the receiver as needed based on proper Standard Precautions when handling or using this device. All parts of the system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and healthcare professionals. For more information, refer to “Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007,” http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html.

If a patient returns a receiver because the shield or seals are torn, damaged or defective, assume that the receiver has been contaminated and discard the receiver, shield, seals and spacer. If a patient returns a receiver because the spacer is torn, damaged or defective, discard the shield, seal and spacer and replace with a new shield, seal and spacer.

chapter six

INSERTING A SENSOR AND STARTING A SENSOR SESSION

6

CHAPTER 6: INSERTING A SENSOR AND STARTING A SENSOR SESSION

You need a sensor, a transmitter, a receiver and a receiver shield to use the Dexcom G4 PLATINUM Professional Continuous Glucose Monitoring System. You also need a blood glucose meter and test strips for calibration. The blood glucose meter and test strips are not provided in the Dexcom G4 PLATINUM Professional System. The sensor continuously measures and displays the sensor glucose readings for up to 7 days when in real-time mode. The following sections will show you how to insert the sensor and start a new continuous glucose monitoring session both in real-time and blinded modes.

WARNING

Sensors may fracture on rare occasions. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the insertion site. If you experience a broken sensor, please report this to our Technical Support department at **1.877.339.2664 or 1.858.200.0200.**

For patients undergoing an MRI with a retained wire broken off from a Dexcom G4 PLATINUM Sensor, in-vitro MRI testing did not detect any safety hazards. There was no significant migration or heating of the wire and imaging artifacts were limited to the area around the wire.

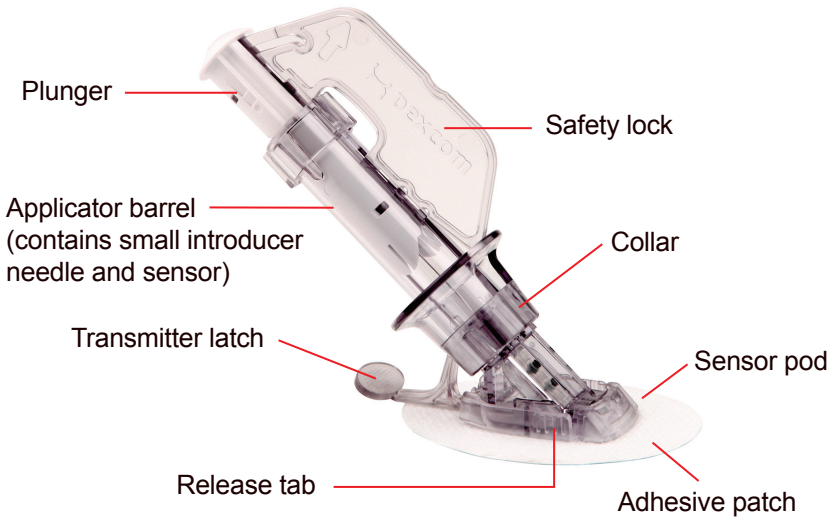
6.1 BEFORE YOU START

- Make sure the correct transmitter ID has been entered into the receiver (see Chapter 5, Section 5.2, The Settings Menu). You do not need to re-enter the transmitter ID each time you start a sensor session.
- Check the expiration date on the sensor package label. The format is YYYY-MM-DD. Insert sensors on or before the end of the expiration date calendar day.
- Follow the blood glucose meter's manufacturer's instructions to make sure you are getting accurate blood glucose values for calibration.
- The healthcare professional must clean and disinfect the transmitter before giving it to a new user (see Chapter 12, Section 12.3, Cleaning and Disinfection of the Transmitter).
- Make sure the blood glucose meter and receiver date and time are correct and match.

WARNING

Store the sensor at temperatures between 36° F - 77° F for the length of the sensor's shelf life. You may store the sensor in the refrigerator if it is within this temperature range. The sensor should not be stored in a freezer. Storing the sensor improperly might cause the sensor glucose readings to be inaccurate, and you might miss a low or high blood glucose value.

Review the sensor applicator picture before using a new sensor.



6.2 REMOVING THE SENSOR FROM ITS PACKAGING

PRECAUTION

Do not use the sensor if its sterile package has been damaged or opened. Using an unsterile sensor might cause infection.

- Wash hands thoroughly, and dry them.
- Carefully remove the sensor from its packaging. Look closely at the sensor to make sure it is not damaged.
- The applicator is for single use and is disposable.
- The safety lock prevents you from releasing the needle accidentally before you are ready.

6.3 CHOOSING AN INSERTION SITE

PRECAUTIONS

- Avoid inserting the sensor in areas that are likely to be bumped, pushed or compressed or areas of skin with scarring, tattoos, or irritation as these are not ideal sites to measure glucose. Insertion in those areas might affect sensor performance, and you might miss a low or high blood glucose value.
- Avoid injecting insulin or placing an insulin pump infusion set within 3 inches of the sensor. The insulin might affect sensor performance, and you might miss a low or high blood glucose value.

Choose a site on the belly to place the sensor. You can choose a site above or below the belt line. The best areas to insert the sensor are usually flat, “pinchable,” and free from where rubbing can occur, such as along the waist band and seat belt strap.

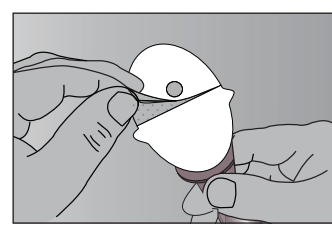
- Choose an area at least 3 inches from the insulin pump infusion set or injection site.
- If more than one sensor is used, avoid using the same spot repeatedly for sensor insertion. Never use the same site for 2 sensor sessions in a row.
- You may need to shave the area where you plan to put the sensor so the adhesive patch sticks securely.
- Make sure there are no traces of lotions, perfumes or medications on the area. Clean the skin with isopropyl alcohol to remove these products from the skin.

6.4 PLACING THE SENSOR

WARNING

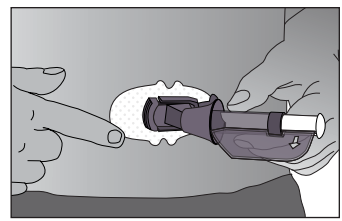
Do not use the Dexcom G4 PLATINUM Professional System for treatment decisions, such as how much insulin you should take. The Dexcom G4 PLATINUM Professional System does not replace a blood glucose meter. Always use the values from your blood glucose meter for treatment decisions. Blood glucose values may differ from sensor glucose readings. Using the sensor glucose readings for treatment decisions could lead to low or high blood glucose value.

1. Clean the skin at the sensor placement site with an alcohol wipe. Make sure the area is clean and completely dry before you insert the sensor.
2. Remove the adhesive backing from the sensor pod one half at a time, using the white tabs on the backing. Hold the sensor by the applicator barrel, and try not to touch the sticky adhesive patch.



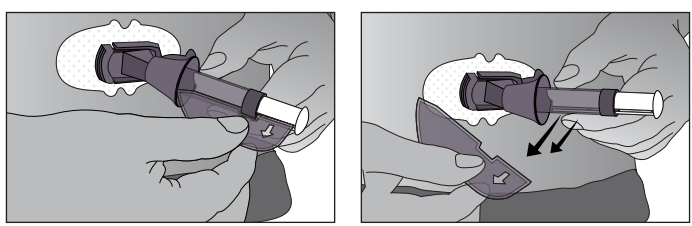
Step 2. Remove the adhesive backing

3. Place the sensor horizontally, NOT vertically, on the skin.
4. Move your fingers around the adhesive patch to secure the tape to the skin.



Step 3 and 4. Adhere the sensor on the skin

5. Hold the applicator, and pull the safety lock straight out away from the applicator, in the direction of the arrows in the picture.



Step 5. Remove the safety lock

6. Save the safety lock to help you remove the transmitter at the end of the sensor session. The safety lock can be used for transmitter removal but is not required. When the glucose monitoring session is over, follow the steps in Chapter 11, Section 11.3, Transmitter Removal, with or without the safety lock.

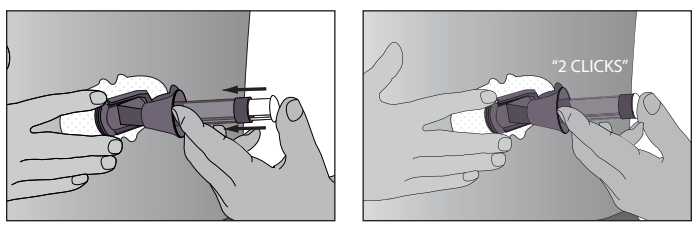
6.5 SENSOR INSERTION

You are ready to insert the sensor after you place the applicator on the belly and remove the safety lock. To insert the sensor follow these steps:

1. Place the fingers of one hand at the edge of the white adhesive (at the opposite side of the sensor from the transmitter latch). You may pinch up on the skin using this hand. Do not pinch up in the middle section of the plastic base.

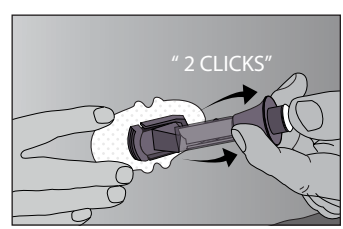
2. While still pinching, use the other hand to place two fingers above the collar on the applicator barrel so they are resting above the collar.
3. Place a thumb on the white plunger. Push the plunger down completely, making sure it is flush against the applicator barrel. You should hear **2 clicks**. This inserts the needle and sensor under the skin.

When you are pushing down on the plunger, do not pull back on the collar.



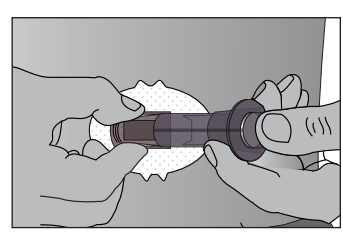
Steps 1-3. Push down the plunger - insert the needle and sensor

4. Keep pinching up on the skin with one hand. With the other hand, place two fingers under the collar. Keep the thumb lightly on top of the white plunger, and pull the collar back towards the thumb until you hear **2 clicks** or cannot pull back any more. This leaves the sensor under the skin and removes the needle from the body.



Step 4. Pull back the collar - retract the needle

5. Squeeze the center of the ribbed release tabs on the sides of the sensor pod to remove the applicator barrel. Only the sensor pod will be left on the body.



Step 5. Release the applicator barrel

- Make sure the transmitter latch is down (against the body) before squeezing the tabs to remove the applicator barrel.
- Squeeze the center of the ribbed part of the release tabs.
- While squeezing the tabs, rock the applicator barrel forward and out away from the body.

If you have any problems with insertion, save the sensor and applicator and contact Dexcom Technical Support (see Chapter 15, User Assistance).

6.6 TRANSMITTER ATTACHMENT

You must snap the transmitter into the sensor pod after you insert the sensor. Follow these steps to attach the transmitter.

1. Ensure the transmitter is free of dust before placing the transmitter in the sensor pod (see Chapter 12, Section 12.3, for cleaning instructions).

Do not to touch the metal circles on the bottom of the transmitter with the skin.

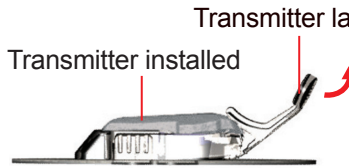
Do not to scratch the bottom of the transmitter as scratches may compromise the waterproof seal.

2. Place the transmitter in the sensor pod (with the flat side down, and the narrower side away from the transmitter latch).

Install transmitter in sensor pod

3. Snap in the transmitter:
   a. With one hand, you may want to pinch up on the skin at the front edge of the white adhesive.
   b. Place one finger on the transmitter to keep it in place.

c. With the other hand, pull the transmitter latch up and forward, over the transmitter, to snap it into place. The transmitter should lie flat in the sensor pod.



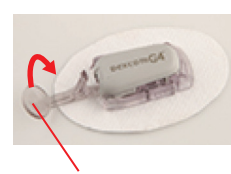
Side view of transmitter in sensor pod

- Make sure you hear **2 clicks** when you snap the transmitter in place. If it is not fully snapped in, this may lead to a poor connection and let fluids to get under the transmitter. This can lead to inaccurate sensor glucose readings or missed sensor glucose readings as shown as ???.

d. Release the pinch on the adhesive edge at this time.

e. Make sure the transmitter is secure by sliding the fingers under each long side of the sensor pod and pressing down on the transmitter with the thumb of the same hand, like you are pinching it.

4. Hold the sides of the sensor pod with one hand. Remove the transmitter latch with the other hand by quickly twisting off the latch away from the body.


Twist transmitter latch up or down

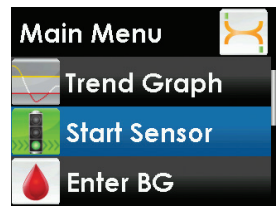
5. Do not remove the transmitter from the sensor pod while the pod is attached to the skin.

6.7 STARTING A SENSOR SESSION

Follow the steps below to tell the receiver that you inserted a new sensor.

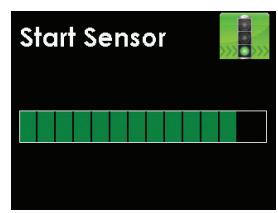
1. Press the **SELECT** button to turn on the receiver.

2. From any trend graph, press the **SELECT** button to see the Main Menu.
3. Press the **DOWN** button to highlight “Start Sensor.”
   - The “Start Sensor” menu option will disappear from the Main Menu after you select it. The option will only come back after an active sensor session ends. If you do not see the “Start Sensor” option on the menu screen, you can continue the current session or stop the session (refer to Chapter 13, Section 13.6, Sensor Shut-off Troubleshooting).



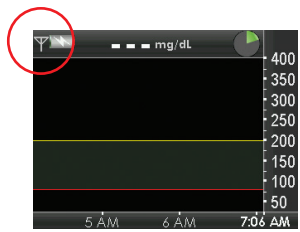
Main Menu,
Start Sensor highlighted

4. Press the **SELECT** button to confirm the start of a new sensor session. The Start Sensor “thinking” screen lets you know the sensor 2-hour startup has begun.

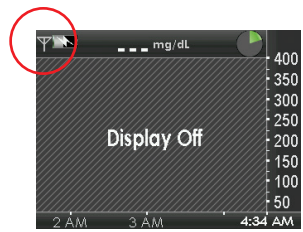


Start Sensor
“thinking“ screen

5. The receiver returns to the 3-hour trend graph.
6. Check the receiver 10 minutes after starting the sensor session to make sure the receiver and transmitter are communicating. The antenna symbol should be in the upper left corner of trend graph. If the out of range symbol shows in the upper right corner of the trend graph, see Chapter 13, Section 13.9, Out of Range/No Antenna.



Antenna symbol should appear in upper left of trend graph in real-time mode



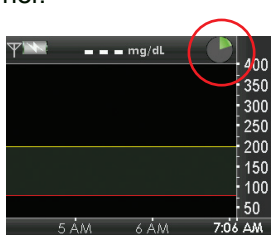
Antenna symbol should appear in upper left of trend graph in blinded mode

7. If in real-time mode, you will not get sensor glucose readings or high/low glucose alerts until the 2-hour startup period ends and you complete the first calibrations. See Chapter 7, Section 7.3, Startup Calibration. If in blinded mode, you will not get sensor glucose readings or high/low glucose alerts during the entire 7-day sensor session.

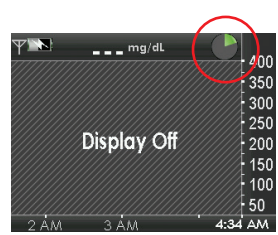
6.8 SENSOR STARTUP PERIOD

The sensor needs a 2-hour startup period to adjust to being under the skin.

The trend graph shows a 2-hour countdown symbol in the upper right corner.



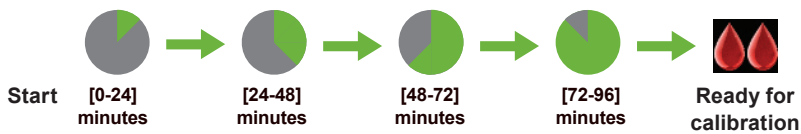
Countdown symbol appears in upper right of trend graph in real-time mode



Counddown symbol appears in upper right of trend graph in blinded mode

1. Press **SELECT** during the startup period to turn the on receiver display and see this symbol.

In both real-time and blinded modes, the countdown symbol fills in over time to show that you are getting closer to the first calibration time. You will not get sensor glucose readings, high/low glucose alerts and alarm during the countdown.



Countdown symbol fills in during sensor startup

If you see the out of range symbol at the top of the screen during the 2-hour startup, review the following troubleshooting tips:

- Make sure the receiver and transmitter are within 20 feet of each other without obstruction. Check in 10 minutes to see if the antenna symbol shows in the upper left corner of the receiver screen.
- If the receiver and transmitter are still not communicating, check the device information screen to make sure the correct transmitter ID is entered into the receiver (see Chapter 5, Section 5.2, The Settings Menu).
- If the correct transmitter ID is in the receiver and the receiver and transmitter are still not communicating, contact Dexcom Technical Support (see Chapter 15, User Assistance).

At the end of the 2-hour startup period the receiver lets you know it is time to calibrate the sensor. Chapter 7, Calibrating the Dexcom G4 PLATINUM Professional System, tells you how to calibrate the sensor.

6.9 TAPING THE SENSOR POD

The sensor pod should stay on the skin using its own adhesive. But, if the patch is peeling up, you can use medical tape (such as Blenderm™, Tegaderm™, Smith & Nephew IV3000®, 3M™ tape) for extra support. If you use tape, only tape over the white adhesive patch on all sides

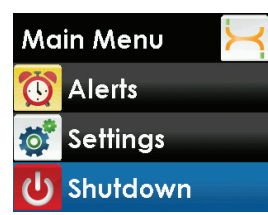
for even support. Do not tape over the transmitter or any of the plastic parts of the sensor pod. Do not tape under the sensor pod or leave any substance on the skin where you insert the sensor.

The right way to use tape for extra support

6.10 TEMPORARY RECEIVER SHUTDOWN

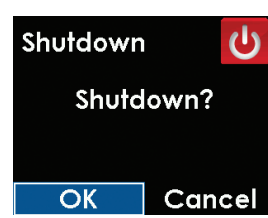
There may be times when you want to shut down the receiver temporarily. Shutdown stops all communication between the transmitter and receiver and turns the receiver off. You will not receive sensor glucose readings or **any** alerts or alarm while the receiver is shut down, but the current sensor session will continue. During the shutdown period, no sensor glucose readings will be recorded or kept in memory. Follow these steps to shut down the receiver:

1. From the main menu, scroll to highlight "Shutdown." Press the **SELECT** button.



Main Menu, Shutdown highlighted

2. Confirm that you want to shut down the receiver.
   a. If you want to shut down, press the **LEFT** button to highlight "OK," and then press the **SELECT** button.
   b. If you want to cancel the shutdown, press the **SELECT** button (with "Cancel" highlighted) to return to the Main Menu.



Shutdown screen, OK highlighted

To turn the receiver back on and resume communication with the transmitter, press and hold the **SELECT** button. It may take up to 20 seconds for the display to turn back on.

Remember that the alerts and low glucose alarm will not work when the receiver is shut down nor will any sensor glucose readings be recorded. All sensor glucose data will be lost.

Shutting down the receiver does not extend the sensor life beyond 7 days. The sensor session will stop 7 days after you started the sensor session. Once you turn the receiver back on from Shutdown mode, you will not need to calibrate or do anything specific to resume.

6.11 THE DEXCOM G4 PLATINUM PROFESSIONAL SYSTEM AND WATER

The sensor is water resistant when showering, bathing or swimming if the transmitter is fully snapped in. The sensor has been tested to be water resistant when submerged for up to 8 feet and up to 24 hours.

Keep the receiver dry. Do not spill fluids on it or drop it into fluids. The receiver shield does not add protection from fluids that may damage the receiver. **Keep the micro USB port cover open throughout the sensor session and keep the square seal over the USB port.** Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub or water bed.

If the receiver gets wet, make sure the speaker and vibrate mode are still working. You can do this using the Try It option in the profiles menu. See Chapter 9, Section 9.3, Alert Profiles.

7

chapter seven

CALIBRATING THE DEXCOM G4 PLATINUM PROFESSIONAL SYSTEM

7

CHAPTER 7: CALIBRATING THE DEXCOM G4 PLATINUM PROFESSIONAL SYSTEM

In both real-time and blinded modes, you must calibrate Dexcom G4 PLATINUM Professional System sensor glucose readings to the blood glucose meter.

CONTRAINDICATION

Taking medications with acetaminophen (such as Tylenol) while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.

7.1 CALIBRATION OVERVIEW

The receiver needs calibrations to display and record accurate continuous sensor glucose readings and trend information. There are important times when you **must** calibrate:

1. 2-hour startup: 2 hours after you insert the sensor
2. 12 hour update: every 12 hours after the 2-hour startup calibration
3. More information needed or other reasons

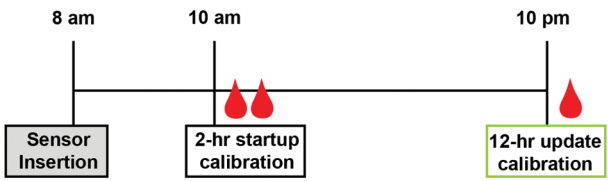
When calibrating, you must enter the blood glucose values into the receiver by hand. You can use any commercially available blood glucose meter. You must calibrate with accurate blood glucose meter values to get accurate sensor glucose readings.

On the first day of the sensor session, you must enter 2 blood glucose values into the receiver. You must enter at least 1 blood glucose value calibration 12 hours after the startup calibration. You must enter 1 blood glucose value every 12 hours throughout the 7-day sensor session. The receiver will remind you when it needs these calibrations. You may be

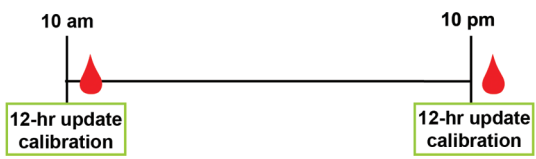
prompted to enter additional blood glucose values as needed.

Example Minimum Calibration Schedule During Seven-Day Sensor Session

Monday (Day One of Sensor Session):



Tuesday - Sunday (Days 2-7 Sensor Session):



Example Minimum Calibration Schedule During Seven-Day Sensor Session

PRECAUTION

Do not use alternative blood glucose site testing (blood from your palm or forearm, etc.) for calibration. Alternative site blood glucose values may be different than those taken from a fingerstick blood glucose value and may not represent the timeliest blood glucose value. Use a blood glucose value taken only from a fingerstick for calibration. Alternative site blood glucose values might affect sensor performance, and you might miss a low or high blood glucose value.

7.2 HOW TO CALIBRATE

You must enter the exact blood glucose value from the meter for each calibration. Blood glucose values used for calibration must be between 40-400 mg/dL and must have been taken within the past 5 minutes.

- In real-time mode, make sure either a sensor glucose reading or a calibration needed symbol shows at the top of the trend graph in the status area before calibrating. In blinded mode, make sure either "- - -" or a calibration needed symbol shows at the top of the trend graph in the status area before calibrating.
- The sensor can be calibrated if the meter glucose is 40 mg/dL or above. For safety reasons, if the blood glucose is low, first treat the low blood sugar.
- Always make sure the antenna symbol is in the upper left corner of the trend graph before you enter blood glucose values for calibration.
- Always use the same meter to calibrate that you routinely use to measure the blood glucose. Do not switch the meter in the middle of a sensor session. Blood glucose meter and strip accuracy vary between blood glucose meter brands.
- The accuracy of the blood glucose meter value used for calibration may affect the accuracy of sensor glucose readings.

WARNING

Calibrate at least once every 12 hours. Calibrating less often than every 12 hours might cause sensor glucose readings to be inaccurate, and you might miss a low or high blood glucose value.

PRECAUTION

Do not calibrate if your blood glucose is changing at a significant rate, typically more than 2 mg/dL per minute. Do not calibrate when your receiver screen is showing the rising single arrow or double arrow, which indicates that your blood glucose is rising 2-3 mg/dL/min or more than 3 mg/dL/min. Also, do not calibrate when your receiver screen is showing the falling single arrow or double arrow, which indicates that your blood glucose is falling 2-3 mg/dL/min or more than 3 mg/dL/min. Calibrating during significant rise or fall of blood glucose may affect accuracy of sensor glucose readings.

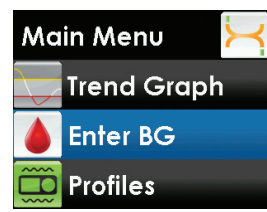
PRECAUTION

To calibrate the system, enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose measurement. Entering incorrect blood glucose values or blood glucose values from more than 5 minutes before entry might affect sensor performance, and you might miss a low or high blood glucose value.

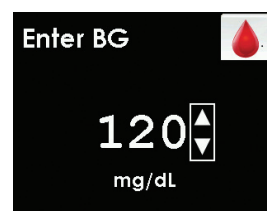
Only use blood glucose values between 40-400 mg/dL for calibration. If the blood glucose value you enter is outside of this range, the receiver will not accept the value for calibration. You must wait until the blood glucose is in this range to calibrate.

These steps show you how to enter the blood glucose values for calibration in both real-time and blinded modes:

1. Wash and dry hands, make sure the glucose test strips are not expired and have been stored properly, and make sure the meter is properly coded (if required).
2. Take a blood glucose measurement using the meter.
   - Carefully apply the blood sample to the test strip following the meter or test strip instructions.
3. From any trend graph, press the **SELECT** button to see the Main Menu.
4. Use the **UP** or **DOWN** button to scroll until you highlight "Enter BG."
   - "Enter BG" will be the second Main Menu option when you are in the middle of a sensor session.
5. Press the **SELECT** button to choose this option. You will see a screen with a blood drop and a number in mg/dL units.
   a. At all times in real-time and blinded modes, when the receiver does not have a recent sensor glucose reading the default is 120 mg/dL.
   b. If there has been a sensor glucose reading in the past 15 minutes in real-time mode, the Enter BG screen shows the current sensor glucose reading. **Do not use the current sensor glucose reading for calibration.** Use only blood glucose values from the meter.
6. Use the **UP** or **DOWN** button to scroll until you see the correct blood glucose value, and then press the **SELECT** button.



Main Menu, Enter BG highlighted



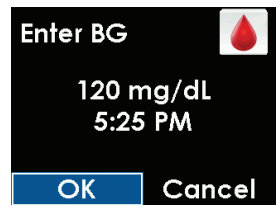
Enter BG screen, default is 120 mg/dL

7. **Confirm that the blood glucose value you entered is correct. Entering incorrect values may affect the sensor accuracy.**

   a. Press the **SELECT** button if the blood glucose value displayed is correct.

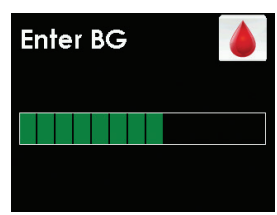
   b. If the blood glucose value shown is incorrect, press the **RIGHT** button to highlight “Cancel” then press the **SELECT** button to return to the Enter BG screen. Repeat the steps to enter the correct blood glucose value.

   c. If you do not press the **SELECT** button, the receiver will “time out” and no blood glucose value will be recorded for calibration.



Enter BG screen,
OK highlighted to confirm

8. The Enter BG “thinking” screen lets you know the blood glucose value is being used for calibration.



Enter BG
“thinking” screen

9. For 2-hour startup calibration, repeat these steps for the second blood glucose value.

A sensor glucose reading appears on the receiver right away, and sensor glucose readings are updated every 5 minutes.

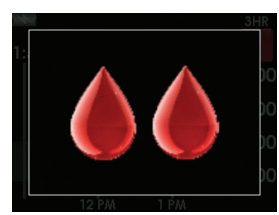
If readings do not appear immediately, see Chapter 13, Section 13.2, Calibration Troubleshooting.

PRECAUTION

To calibrate the system, enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose measurement. Entering incorrect blood glucose values or blood glucose values from more than 5 minutes before entry might affect sensor performance, and you might miss a low or high blood glucose value.

7.3 STARTUP CALIBRATION

Two hours after you start the sensor session (see Chapter 6, Section 6.7, Starting a Sensor Session) the receiver tells you that you need to calibrate by showing the startup calibration prompt. This means you need to calibrate with 2 separate blood glucose values from the meter. **If used in real-time mode, the receiver will not show sensor glucose readings until the receiver accepts the blood glucose values for calibration. If used in blinded mode, the receiver will not show sensor glucose readings throughout the 7-day sensor session. However, the receiver will confirm that it is properly recording sensor glucose readings every 5 minutes by showing "- - -" in the status area of the receiver screen.**



Startup calibration prompt

"- - -" in status area

1. The receiver will alert you based on the alert profile setting chosen. When you see this screen, press the **SELECT** button to clear it.

a. The startup calibration symbol will stay at the top of the trend graph until you calibrate.

b. The system will re-alert you every 15 minutes until you enter the blood glucose values.

c. If you do not clear the prompt, the system will re-alert you every 5 minutes.

2. Take 2 separate blood glucose measurements with the blood glucose meter, and enter the blood glucose values into the receiver (see Chapter 7, Section 7.2, How to Calibrate).

7.4 12-HOUR CALIBRATION UPDATE

Calibrate the system at least every 12 hours after the first calibration (2-hour startup calibration) to make sure the sensor glucose readings remain accurate and close to the blood glucose meter values. You can enter blood glucose values earlier than 12 hours if you want. If you have not entered any blood glucose values in the past 12 hours, the receiver will prompt you to enter a blood glucose value to update its calibration by displaying the calibration prompt.

NOTE: The 12-hour calibration update will not audibly alert you to the need to calibrate. A calibration prompt will silently appear on the receiver screen to let you know it is time to calibrate.

WARNING

Calibrate at least once every 12 hours. Calibrating less often than every 12 hours might cause sensor glucose readings to be inaccurate, and you might miss a low or high blood glucose value.

The following steps show you how to enter this calibration.

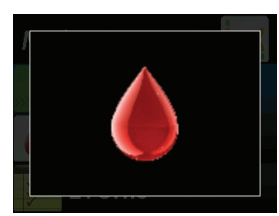
Calibration prompt

1. When you see this screen, press the **SELECT** button to clear it.
   a. The calibration needed symbol will stay at the top of the trend graph until you calibrate.
   b. The system will silently prompt you every 15 minutes until you enter the blood glucose values.
2. Take 1 blood glucose measurement with the meter, and enter the blood glucose value into the receiver. If this screen reappears soon, see Chapter 13, Section 13.2, Calibration Troubleshooting.

7.5 OTHER REASONS YOU MAY NEED TO CALIBRATE

You may need to calibrate when the system did not accept the last calibration or the blood glucose value is very different from the sensor glucose reading.

When you see this calibration prompt it means it is time to calibrate with a single blood glucose value.



Calibration prompt

Take 1 blood glucose measurement with the meter, and enter the blood glucose into the receiver. If this screen reappears soon, see Chapter 13, Section 13.2.1, Types of Calibration Prompts.

These screens show calibration errors (see Chapter 13, Section 13.3, Calibration Error Troubleshooting).

Wait 15 minutes
calibration error screen

Wait 1 hour
calibration error screen

chapter eight

VIEWING SENSOR GLUCOSE READINGS AND TRENDS IN REAL-TIME MODE

CHAPTER 8: VIEWING SENSOR GLUCOSE READINGS AND TRENDS IN REAL-TIME MODE

This chapter teaches you how to view the sensor glucose readings and trend information. The trend graph provides additional information that the blood glucose meter does not. It shows the current glucose value, the direction it is changing and how fast it is changing. The trend graph can also show you where the glucose has been over time.

NOTE: In blinded mode, sensor glucose readings will not be displayed to the patient throughout the 7-day sensor session. The sensor glucose readings and glucose patterns can be downloaded and reviewed later with a healthcare professional using the Dexcom STUDIO software.

CONTRAINDICATION

Taking medications with acetaminophen (such as Tylenol) while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.

The blood glucose meter and sensor measure glucose from two different types of body fluids: blood and interstitial fluid. Therefore, readings from the blood glucose meter and sensor may not match.

The greatest benefit you get from using the Dexcom G4 PLATINUM Professional System used in real-time mode will come from the trending information. It is important that you focus on the trends and rate of change on the receiver, rather than the exact sensor glucose reading.

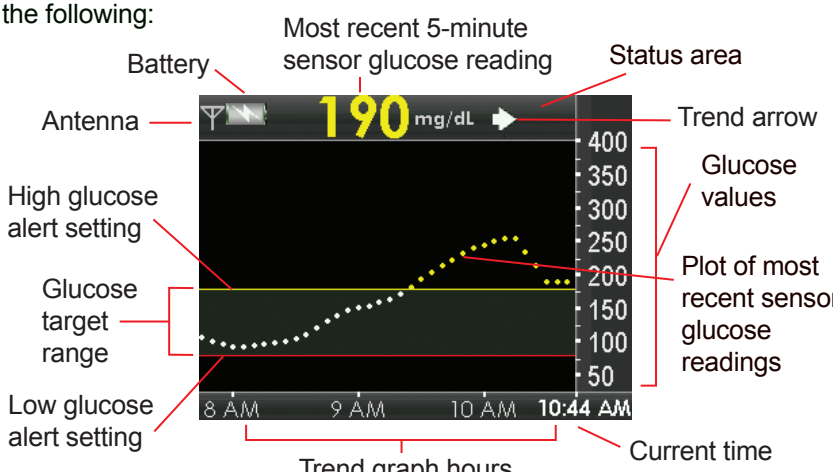
If you have trouble reading the receiver in bright sunlight, find a shady spot.

WARNING

Do not use the Dexcom G4 PLATINUM Professional System for treatment decisions, such as how much insulin you should take. The Dexcom G4 PLATINUM Professional System does not replace a blood glucose meter. Always use the values from your blood glucose meter for treatment decisions. Blood glucose values may differ from sensor glucose readings. Using the sensor glucose readings for treatment decisions could lead to low or high blood glucose value.

8.1 SENSOR GLUCOSE READINGS IN REAL-TIME MODE

Press the **SELECT** button to wake up the receiver screen and see the home screen (the 3-hour trend graph). The 3-hour trend graph shows the following:

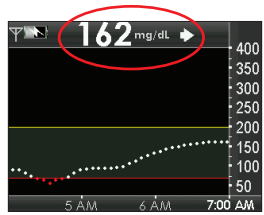


EXAMPLE: 3-Hour Trend Graph Screen

- Each “dot” on the trend graph is a sensor glucose reading reported every 5 minutes.
- The trend graph shows the current time.
- The status area shows needed calibration updates, calibration errors and sensor glucose reading issues.
- The high alert setting shows as a yellow line across the trend graph.
- The low alert setting shows as a red line across the trend graph.
- The gray zone highlights the target glucose range, based on the high and low glucose alert settings.
- The current sensor glucose reading is red if it is low and yellow if it is high, based on the high and low glucose alert settings.
- If the low glucose alert is not set and the user’s glucose is 55 mg/dL or lower, the glucose value is red.
- If the sensor glucose readings are in between the high and low glucose alert settings, the glucose value is white.
- The dots on the trend graph change colors based on the high and low alert settings.

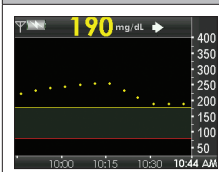
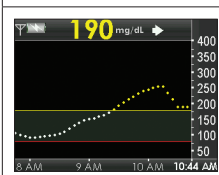
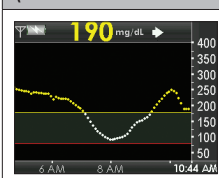
You can view the past glucose information on the 1, 3, 6, 12, and 24 hour trend graphs by pressing the **UP** or **DOWN** button.

- The system only reports glucose information between 40-400 mg/dL. The trend graph shows a flat line or dots at 400 or 40 mg/dL when the glucose is outside this range. If the sensor glucose reading is less than 40 mg/dL the receiver will read “LOW”; if the sensor glucose reading is greater than 400 mg/dL, the receiver will read “HIGH.”



The sensor glucose reading is in milligrams per deciliter (mg/dL) unit

Which Trend Graph Do You See?

(Scroll up from the 3-hour graph to reach the 1-hour graph)	
	**1-Hour Trend Graph:** The 1-hour trend graph shows the current sensor glucose reading and the last 1 hour of sensor glucose readings.
	**3-Hour Trend Graph:** The 3-hour trend graph shows the current sensor glucose reading and the last 3 hours of sensor glucose readings.
(Scroll down from the 3-hour graph to reach the 6-hour graph)	
	**6-Hour Trend Graph:** The 6-hour trend graph shows the current sensor glucose reading and the last 6 hours of sensor glucose readings.

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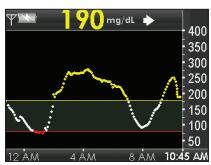
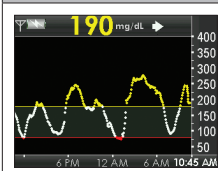
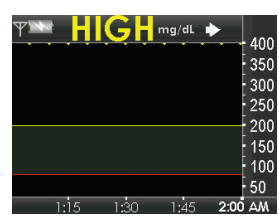
Which Trend Graph Do You See? (continued from page before)

(Scroll down from the 6-hour graph to reach the 12-hour graph)
 **12-Hour Trend Graph:** The 12-hour trend graph shows the current sensor glucose reading and the last 12 hours of sensor glucose readings.
(Scroll down from the 12-hour graph to reach the 24-hour graph)
 **24-Hour Trend Graph:** The 24-hour trend graph shows the current sensor glucose reading and the last 24 hours of sensor glucose readings.

The receiver displays “LOW” when the most recent sensor glucose reading is less than 40 mg/dL and “HIGH” when the most recent sensor glucose reading is greater than 400 mg/dL.

Trend graph reading LOW



Trend graph reading HIGH

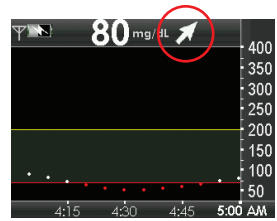
8.2 RATE OF CHANGE ARROWS IN REAL-TIME MODE

The rate of change arrows add detail about the direction and speed of glucose change over the last 15-20 minutes.

The trend arrows show to the right of the current sensor glucose reading.

Do not overreact to the rate of change arrows. Consider recent insulin dosing, activity, food intake, the overall trend graph and the blood glucose value before taking action.

If there are missed communications between the sensor and receiver during the last 15-20 minutes, an arrow may not display.



Rate of change arrow appears in upper right of trend graph

This table shows the different trend arrows the receiver displays:

Trend Arrows

→	**Constant:** The glucose is steady (not increasing/decreasing more than 1 mg/dL each minute). The glucose could increase or decrease by up to 15 mg/dL in 15 minutes.
↗	**Slowly rising:** The glucose is rising 1-2 mg/dL each minute. If it continued rising at this rate, the glucose could increase up to 30 mg/dL in 15 minutes.
↑	**Rising:** The glucose is rising 2-3 mg/dL each minute. If it continued rising at this rate, the glucose could increase up to 45 mg/dL in 15 minutes.
⇈	**Rapidly rising:** The glucose is rising more than 3 mg/dL each minute. If it continued rising at this rate, the glucose could increase more than 45 mg/dL in 15 minutes.
↘	**Slowly falling:** The glucose is falling 1-2 mg/dL each minute. If it continued falling at this rate, the glucose could decrease up to 30 mg/dL in 15 minutes.

(continued on next page)

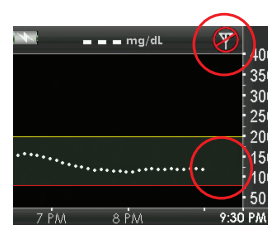
Trend Arrows (continued from page before)

↓	**Falling:** The glucose is falling 2-3 mg/dL each minute. If it continued falling at this rate, the glucose could decrease up to 45 mg/dL in 15 minutes.
↓↓	**Rapidly falling:** The glucose is falling more than 3 mg/dL each minute. If it continued falling at this rate, the glucose could decrease more than 45 mg/dL in 15 minutes.
No arrow	**No rate of change information:** The receiver cannot calculate how fast the glucose is rising or falling at this time.

Trend arrows show to the right of the sensor glucose reading. They tell you more about the glucose's speed and direction.

Trend arrows do not show when there are glucose data gaps (see Chapter 13, Section 13.4, System Glucose Error). If the glucose reading error symbol ???, the wait symbol, the out of range symbol, or the calibration needed symbol show at the top of the trend graph, the trend arrows will not show.

If the trend arrow is missing, but you are concerned that the blood glucose level may be rising or falling, take a blood glucose measurement test on the blood glucose meter.



Trend graph with out of range symbol in upper right and glucose data gaps

WARNING

Do not ignore symptoms of high and low glucose. If your sensor glucose readings do not match your symptoms, measure your blood glucose with a blood glucose meter even if your sensor is not reading in the high or low range, so you do not miss a low or high blood glucose value.

8.3 GLUCOSE STATUS AREA SYMBOLS IN BOTH REAL-TIME AND BLINDED MODES

The “status area” at the top of the trend graph may show any of the status symbols below during the sensor session. You will not get sensor glucose readings during the time a status symbol shows except during the regular 12-hour calibration prompt or if the receiver is in blinded mode. See Chapter 8, Section 8.1, Sensor Glucose Readings in Real-Time Mode, for receiver display status area.

Status Symbols

Calibration Needed	This symbol means you need to enter a calibration. This prompt will show when it is time for the 12-hour calibration update or any other time an additional calibration is needed (see Chapter 7, Section 7.2, How to Calibrate).
Additional Startup Calibration Needed	This symbol means you need to enter one more blood glucose value in order to calibrate the system and start getting sensor glucose readings.

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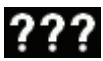
Status Symbols (continued from page before)

 Glucose Reading Error	This symbol means the receiver does not understand the sensor signal but is likely to recover. This symbol is related to the sensor only. You should wait for more prompts and **do not enter** any blood glucose values when you see this symbol (see Chapter 13, Section 13.4, System Glucose Error, for more information).
Out of Range	This symbol means the receiver and sensor/transmitter are not communicating. Make sure the receiver and sensor/transmitter are within 20 feet of each other without obstruction (see Chapter 1, Section 1.4, Transmitter Overview).
Wait 15 Minutes Calibration Error	This symbol means the sensor cannot calibrate right now. If you see this screen, enter at least one more calibration blood glucose value after about 10-15 minutes. If the sensor still cannot calibrate after that, the sensor needs to be removed and a new sensor needs to be inserted.
Wait 1 Hour Calibration Error	This symbol means the sensor is not calibrating correctly. If you see this screen, wait a minimum of one hour and then enter one more blood glucose value. If no readings display on the receiver after this, the sensor needs to be removed and a new sensor needs to be inserted.
Wait	This symbol means the receiver has detected a potential significant problem with the sensor signal and may result in a sensor failure. You should wait about 30 minutes for more prompts. Do not enter any blood glucose values when you see this symbol.

Status symbols show in the upper right of the trend graph.

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chapter nine

ALERTS, ALARM & PROFILES

CHAPTER 9: ALERTS, ALARM & PROFILES

This chapter teaches you about the Dexcom G4 PLATINUM Professional CGM System's many alerts and alarm and how to set them.

9.1 SETTING THE ALERTS IN REAL-TIME MODE

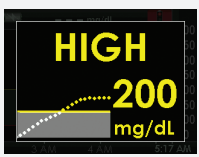
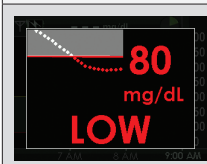
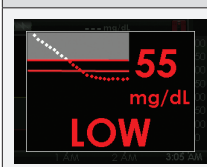
WARNING

Low/high glucose alerts and the 55 mg/dL low glucose alarm are all disabled when using the Dexcom G4 PLATINUM Professional System in blinded mode and will not alert you when the glucose is low or high. Check blood glucose meter if there are any signs or symptoms of low or high glucose.

9.1.1 DEFAULT ALERT/ALARM SETTINGS

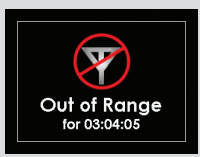
The following alerts and alarms are preset on the receiver.

Default Alert/Alarm Settings in Real-Time Mode

What will I see on the receiver screen?	What does this mean?	What is the default setting?	How will the receiver notify me?	Will the receiver re-notify me?
	**High Glucose Alert** The most recent sensor glucose reading is at or above the high alert setting.	On at 200 mg/dL	Vibrates 2 times and then vibrates/beeps 2 times every 5 minutes until confirmed or the glucose value drops below the alert level.	No, unless you have turned on the high alert snooze feature.
	**Low Glucose Alert** The most recent sensor glucose reading is at or below the low alert setting.	On at 80 mg/dL	Vibrates 3 times and then vibrates/beeps 3 times every 5 minutes until confirmed or the glucose value goes above the alert level.	No, unless you have turned on the low alert snooze feature.
	**Low Glucose Alarm** The most recent sensor glucose reading is at or below 55 mg/dL	On	Vibrates 4 times and then vibrates/beeps 4 times every 5 minutes until confirmed or the glucose value goes above 55 mg/dL.	Yes, every 30 minutes after each confirmation until the blood glucose value comes back into range.

(continued on next page)

Default Alert/Alarm Settings (continued from page before)

What will I see on the receiver screen?	What does this mean?	What is the default setting?	How will the receiver notify me?	Will the receiver re-notify me?
	**Out of Range Alert** The sensor/transmitter and receiver are not communicating to each other.	Off	The alert will not notify you. You must change the settings to receive this alert.	No
 	Rise/Fall Alert Single Arrow The glucose is rising/falling at or above a rate of 2 mg/dL/min (at least 30 mg/dL in 15 minutes).	Off	The alert will not notify you. You must change the settings to receive this alert.	No
 	Rise/Fall Alert Double Arrow The glucose is rising/falling at or above a rate of 3 mg/dL/min (at least 45 mg/dL in 15 minutes).	Off	The alert will not notify you. You must change the settings to receive this alert.	No

This table describes the receiver alerts and alarm and explains how the receiver will notify you in the default setting. The only alert in this table that can be activated in blinded mode is the out of range alert.

The receiver may alert you at other times you need to take action, such as low battery, failed sensor, etc. See Chapter 18, Appendix I, for a detailed list of these other alerts.

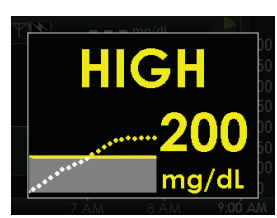
9.1.2 GLUCOSE ALERTS AND ALARM IN REAL-TIME MODE

The Dexcom G4 PLATINUM Professional System lets you create personal settings for how you want the receiver to tell you what is going on if the receiver is used in real-time mode. The low and high glucose alerts tell you when the sensor glucose readings are outside the target glucose range. Rise and fall (rate of change) alerts let you know when the glucose levels are changing fast (see Chapter 9, Section 9.2, Advanced Alerts). The Dexcom G4 PLATINUM Professional System also has a 55 mg/dL low glucose alarm that cannot be changed or turned off. This safety feature tells you the glucose level may be dangerously low. You can set high and low glucose alerts to vibrate and beep. This feature can help during sleeping, driving, exercising or during meetings.

When you have both the high and low alerts turned on, a gray zone on the trend graph shows the target range.

9.1.2.1 HIGH GLUCOSE ALERT IN REAL-TIME MODE

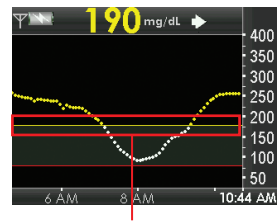
When the sensor glucose readings are at or above the high alert level, this screen shows the high glucose alert level. The receiver vibrates and/or beeps depending on the profile setting (see Chapter 9, Section 9.3, Alert Profiles). This level shows as a yellow line on the trend graph.



High glucose alert set at 200 mg/dL

The receiver continues to alert until you press the **SELECT** button to clear the alert or until the

sensor glucose readings drop below the high glucose alert level. You can have the receiver re-alert after clearing the alert (to change the snooze settings see Chapter 9, Section 9.2, Advanced Alerts).

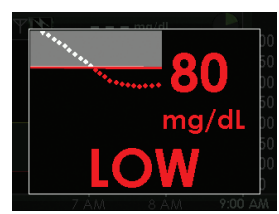


High glucose alert setting

9.1.2.2 LOW GLUCOSE ALERT IN REAL-TIME MODE

When the sensor glucose readings are at or below the low alert level, this screen shows the low glucose alert level. The receiver vibrates and/or beeps depending on the profile setting. This level shows as a red line on the trend graph.

The receiver continues to alert until you press the **SELECT** button to clear the alert or until the sensor glucose readings rise above the low glucose alert level. You can have the receiver re-alert after clearing the alert (to change the snooze settings see Chapter 9, Section 9.2, Advanced Alerts).



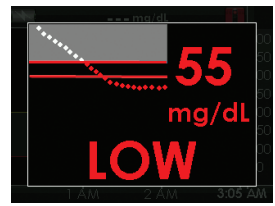
Low glucose alert set at 80 mg/dL

Low glucose alert setting

9.1.2.3 LOW GLUCOSE ALARM IN REAL-TIME MODE

The Dexcom G4 PLATINUM Professional System also has a fixed low alarm at 55 mg/dL. This is different than the low glucose alert. You cannot change or turn off this alarm or its re-alarm settings.

- The receiver displays the low glucose alarm screen.
- Re-alarm: The receiver automatically alerts again 30 minutes after you press the **SELECT** button to clear it, if the sensor glucose readings are still at or below 55 mg/dL.
- The receiver does not alert for reading below 55 mg/dL if you calibrated in the last 5 minutes.

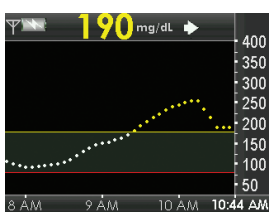


Low glucose alarm

- The receiver alerts if the sensor glucose reading stays outside the target range after five minutes.

9.1.3 GETTING TO THE ALERTS MENU FOR BOTH REAL-TIME AND BLINDED MODES

1. Press the **SELECT** button to turn on the receiver. The 3-hour trend graph shows.

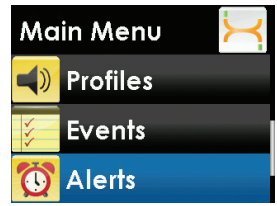


Trend graph in real-time mode

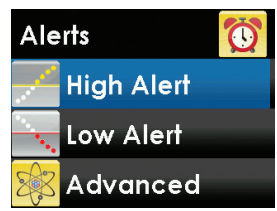
Trend graph in blinded mode

2. Press the **SELECT** button to see the Main Menu.

3. From the Main Menu, press the **UP** or **DOWN** button to scroll to “Alerts,” and press the **SELECT** button. The Alerts menu shows.



Main Menu,
Alerts highlighted



Alerts menu,
High Alert highlighted

9.1.4 CHANGING THE HIGH AND LOW GLUCOSE ALERTS

WARNING

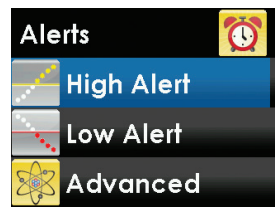
Low/high glucose alerts and the 55 mg/dL low glucose alarm are all disabled when using the Dexcom G4 PLATINUM Professional System in blinded mode and will not alert you when the glucose is low or high. Check blood glucose meter if there are any signs or symptoms of low or high glucose.

The steps for changing both the high alert and the low alert are the same.

NOTE: Changing the high and low glucose alert is not necessary in blinded mode as the high/low glucose alerts are disabled.

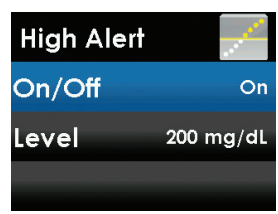
The following steps show you how to change the high and low alert settings.

1. From the Alerts menu, press the **UP** or **DOWN** button to select “High Alert” or “Low Alert” and press the **SELECT** button.

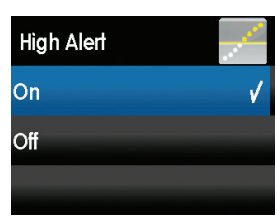


Alerts menu,
High Alert highlighted

2. Highlight “On/Off,” and then press the **SELECT** button to set this option. A check mark shows next to the current setting.



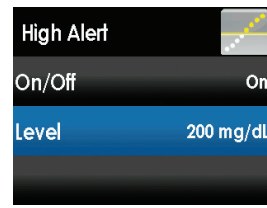
High Alert menu,
On/Off highlighted,
On selected



High Alert menu,
On selected

3. Press the **LEFT** button to return to the last screen.

4. Press the **DOWN** button to highlight “Level.” The number that shows is the current high glucose alert level.



High Alert menu, Level highlighted

5. To change this number, press the **SELECT** button, and then press the **UP** or **DOWN** button to select the high glucose alert level.
   - The high glucose alert value can be set between 120 and 400 mg/dL in 10 mg/dL steps.
   - The low glucose alert value can be set between 60 and 100 mg/dL in 5 mg/dL steps.

High Alert setting screen, 200 mg/dL selected

6. Press the **SELECT** button to confirm the alert level.
7. Press the **LEFT** button to return to the Alerts menu when you finish.

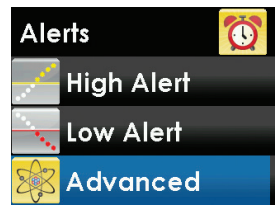
9.2 ADVANCED ALERTS

Advanced alerts include the high and low snooze, rise and fall rate, and out of range alerts. All advanced alerts follow the following steps.

NOTE: The only advanced alerts that can be activated in blinded mode is the out of range alert.

1. Press the **SELECT** button to turn on the receiver.
2. Press the **SELECT** button to enter the Main Menu.
3. Press the **UP** or **DOWN** button to highlight “Alerts,” and press the **SELECT** button.

4. From the Alerts menu, press the **UP** or **DOWN** button to select “Advanced,” and press the **SELECT** button.

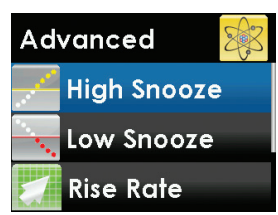


Alerts menu,
Advanced highlighted

9.2.1 SETTING A SNOOZE TIME FOR THE HIGH AND LOW GLUCOSE ALERTS IN REAL-TIME MODE

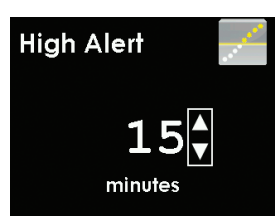
The snooze feature lets you delay the high and low glucose re-alerts. You have the option to set a snooze time for every 15 minutes for up to 5 hours.

1. Press the **UP** or **DOWN** button to highlight “High Snooze” or “Low Snooze” and press the **SELECT** button.



Advanced menu,
High Snooze highlighted

2. Press the **UP** or **DOWN** button to select the amount of time (in 15 minute steps) between the first alert and re-alerts. Press the **SELECT** button.
   - **If you set the amount of time to zero there will be no re-alerts**.



High Alert setting screen,
15 minutes selected

3. Press the **LEFT** button to return to the Alerts menu when you finish.

9.2.2 RISE AND FALL GLUCOSE RATE ALERTS IN REAL-TIME MODE

Rate alerts tell you when the glucose levels are rising (rise alert) or falling (fall alert) and by how much. You can choose for the receiver to alert when the sensor glucose reading is rising or falling 2 mg/dL or more per minute, or 3 mg/dL or more per minute.

If you set the fall rate to 2 mg/dL per minute and the sensor glucose readings fall at this rate or faster, the “FALLING single arrow” screen shows, and the receiver vibrates or beeps in line with the profile settings.

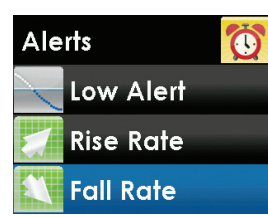
Fall alert

If you set the rise rate to 3 mg/dL per minute and the sensor glucose readings rise at this rate or faster, the “RISING double arrow” screen shows, and the receiver vibrates or beeps in line with the profile settings.

Rapid Rise alert

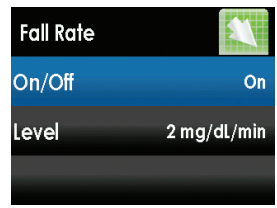
These steps show how to change the rise or fall rate alert settings.

1. Press the **UP** or **DOWN** button to choose “Rise Rate” or “Fall Rate,” and press the **SELECT** button.



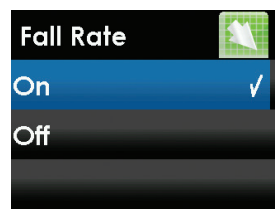
Alerts menu,
Fall Rate highlighted

2. Highlight “On/Off” and then press the **SELECT** button.



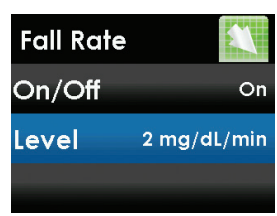
Fall Rate menu,
On/Off highlighted

3. Press the **UP** or **DOWN** button to choose “On” or “Off.” Then, press the **SELECT** button to select “On” or “Off.”



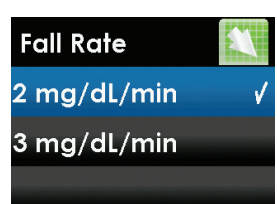
Fall Rate menu,
On selected

4. Press the **LEFT** button to go back to the last screen. Highlight “Level” and then press the **SELECT** button.



Fall Rate menu,
Level highlighted

5. Choose “2 mg/dL/min” (2 mg/dL or more per minute) or “3 mg/dL/min” (3 mg/dL or more per minute). Press the **SELECT** button.



Fall Rate menu,
2 mg/dL/min selected

6. Press the **LEFT** button to return to the alerts menu when you finish.

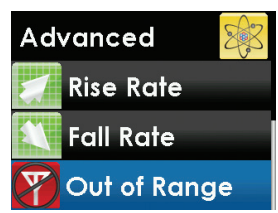
9.2.3 SETTING THE OUT OF RANGE ALERT FOR BOTH REAL TIME AND BLINDED MODES

The out of range alert lets you know when the transmitter and receiver are not communicating with each other. Keep the transmitter and receiver within 20 feet of each other without obstruction. When the transmitter and receiver are too far apart, you will not get sensor glucose readings.

The out of range symbol in the upper right corner of the trend graph and the Out of Range alert screen show when the transmitter and receiver are not communicating. The amount of time out of range shows on the Out of Range alert screen. It will continue to re-alert until they are back in range.

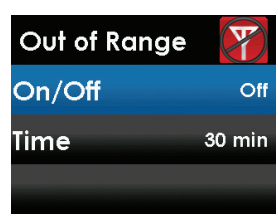
Out of Range alert screen

1. Press the **UP** or **DOWN** button to choose "Out of Range," and press the **SELECT** button.



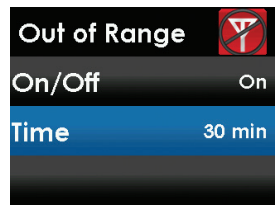
Advanced menu,
Out of Range highlighted

2. Press the **UP** or **DOWN** button to choose "On/Off." Then, press the **SELECT** button to select "On." If you do not want to get out of range alert press the **SELECT** button again to choose "Off."



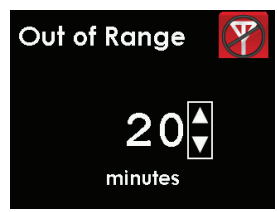
Out of Range menu,
On/Off highlighted

3. Press the **UP** or **DOWN** button to choose "Time," and press the **SELECT** button.



Out of Range menu,
Time highlighted

4. Press the **UP** or **DOWN** button to choose the amount of time out of range after which the receiver will alert (20-200 minutes). Press the **SELECT** button.

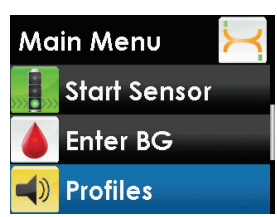


Out of Range setting screen,
20 minutes selected

5. Press the **LEFT** button to return to the Alerts menu when you finish.

9.3 ALERT PROFILES

The Dexcom G4 PLATINUM Professional System lets you set profiles to choose the way you want the alerts to act. This feature is found under the Profiles option on the Main Menu. You can set the profile to the sound pattern and volume that fits the user's needs.



Main Menu,
Profiles highlighted

The profile options are:
1. Vibrate
2. Soft
3. Normal
4. Attentive
5. HypoRepeat

NOTE: For each profile option, the first alert is vibration only.

Regardless of which alert profile you choose, if you confirm the first vibrate alert, you will not get a sound alert.

When you choose the profile setting this setting applies to all alerts, alarm and prompts.

Within each profile setting, each alert has its own unique sound pattern, tone and volume level. This lets you to easily identify each alert and alarm and its meaning.

The fixed low alarm at 55 mg/dL cannot be turned off or adjusted. It is disabled in blinded mode.

The soft, normal, attentive and HypoRepeat profiles have the following alert sequence:

- The first alert is vibrate only.
- If the alert is not confirmed in five minutes, the system vibrates and beeps.
- If the alert is not confirmed in five more minutes, the system vibrates and beeps louder. This continues at the same volume every five minutes until confirmed.

For the HypoRepeat profile in real-time mode only:

- If the alert is confirmed and the sensor glucose readings continue to be at or below 55 mg/dL the system repeats the alert sequence in 30 minutes.

Press the **SELECT** button to confirm any alert.

9.3.1 ALERT PROFILE OPTIONS

Vibrate profile: when you want to silence the receiver and be alerted by vibration. The only exception to this is the fixed low alarm at 55 mg/dL in real-time mode, which alerts you as a vibration first, followed by beeps 5 minutes later if not confirmed.

(continued on next page)

ALERT PROFILE OPTIONS (continued from page before)

Soft profile: when you need the alert to be less noticeable. This profile sets all the alerts and alarm to lower volume beeps.

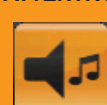
Normal profile: the default profile when you receive the system. This profile sets all alerts and alarms to higher volume beeps.

Attentive profile: when you need the alert to be the most noticeable. This profile sets all the alerts and alarm to loud and highly distinctive melodies.

"HypoRepeat" profile: very similar to the normal profile, but it continuously repeats the fixed low alarm every 5 seconds until the sensor glucose reading rises above 55 mg/dL or is confirmed. This profile is only applicable if the receiver is used in real-time mode and can be helpful if you want extra alerts for severe low sensor glucose readings.

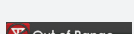
The "Try It" feature is found under the Profiles menu and lets you hear an example of each alert and alarm.

9.3.2 ALERT PROFILE DETAILS

PROFILE TYPE	VIBRATE	SOFT	NORMAL	ATTENTIVE 	HYPOREPEAT
High Alert In Real-Time Mode Only	2 long vibrates	2 long vibrates + 2 low beeps	2 long vibrates + 2 medium beeps	2 long vibrates + ascending melody	2 long vibrates + 2 medium beeps

(continued on next page)

ALERT PROFILE DETAILS (continued from page before)

PROFILE TYPE	VIBRATE	SOFT	NORMAL	ATTENTIVE	HYPOREPEAT
Low Alert In Real-Time Mode Only	3 short vibrates	3 short vibrates + 3 low beeps	3 short vibrates + 3 medium beeps	3 short vibrates + descending melody	3 short vibrates + 3 medium beeps
Rise Alert In Real-Time Mode Only	2 long vibrates	2 long vibrates + 2 low beeps	2 long vibrates + 2 medium beeps	2 long vibrates + 1 short ascending melody	2 long vibrates + 2 medium beeps
Fall Alert In Real-Time Mode Only	3 short vibrates	3 short vibrates + 3 low beep	3 short vibrates + 3 medium beeps	3 short vibrates + 2 short descending melodies	3 short vibrates + 3 medium beeps
Out of Range Alert In Both Real-Time and Blinded Modes 	1 long vibrate	1 long vibrate + 1 low beep	1 long vibrate + 1 medium beep	1 long vibrate + 3 short repeating melodies	1 long vibrate + 1 medium beep

(continued on next page)

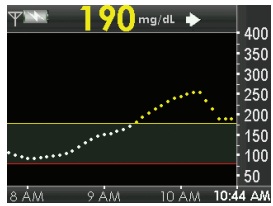
ALERT PROFILE DETAILS (continued from page before)

PROFILE TYPE	VIBRATE	SOFT	NORMAL	ATTENTIVE	HYPOREPEAT
Fixed Low In Real-Time Mode only	4 short vibrates + 4 medium tone beeps	4 short vibrates + 4 medium tone beeps	4 short vibrates + 4 medium tone beeps	4 short vibrates + 2 long descending melodies + pause + 4 low beeps	4 short vibrates + 4 low beeps + pause + repeat sequence
All Other Alerts In Both Real-Time and Blinded Modes	1 long vibrate	1 long vibrate + 1 low beep	1 long vibrate + 1 medium beep	1 long vibrate + 1 short melody	1 long vibrate + 1 medium beep

Other alerts are calibration error, low battery, transmitter low battery, transmitter failure, calibration required, sensor failure, system check, 30-minute replace sensor and replace sensor now.

These steps show you how to select the profile you want.

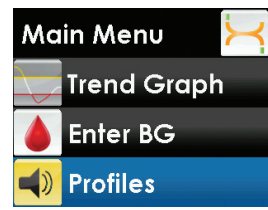
1. Press the **SELECT** button to turn on the receiver. The 3-hour trend graph will show.



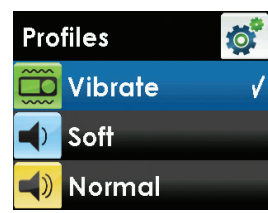
Trend graph in real-time mode

Trend graph in blinded mode

2. Press the **SELECT** button to see the Main Menu.
3. Press the **UP** or **DOWN** button to scroll to "Profiles," and press the **SELECT** button. The Profiles menu will show
4. Press the **UP** or **DOWN** button to scroll to the profile you want to set, and press the **SELECT** button.
5. Press the **LEFT** button to return to the Main Menu when you finish.



Main Menu, Profiles highlighted



Profiles menu, Vibrate highlighted

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10

chapter ten

EVENTS, DEXCOM STUDIO SOFTWARE AND BLINDED MODE

10

CHAPTER 10: EVENTS, DEXCOM STUDIO SOFTWARE AND BLINDED MODE

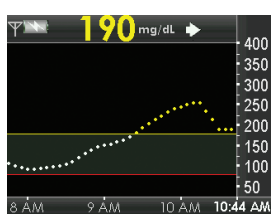
The Events feature lets you record information that may help users and healthcare professionals better understand glucose patterns and trends. Event markers can be used in both real-time and blinded mode. You can enter details about carbohydrates, insulin, exercise, and health issues. You can view these events with the trends and patterns later with a healthcare professional when the receiver is downloaded using the Dexcom STUDIO software.

10.1 EVENTS

Event markers can be downloaded and viewed in the Dexcom STUDIO software but cannot be viewed on the receiver.

10.1.1 SELECTING AN EVENT

1. Press the **SELECT** button to turn on the receiver. The 3-hour trend graph will show.

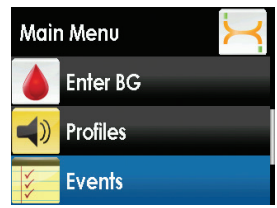


Trend graph in real-time mode

Trend graph in blinded mode

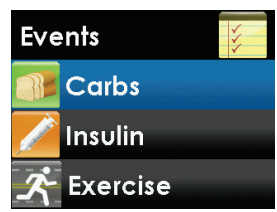
2. Press the **SELECT** button to see the Main Menu.

3. Press the **UP** or **DOWN** button to scroll to "Events," and press the **SELECT** button. The Events menu will show.



Main Menu,
Events highlighted

4. Press the **UP** or **DOWN** button to choose the event you want: "Carbs," "Insulin," "Exercise" or "Health." Press the **SELECT** button.



Events menu,
Carbs highlighted

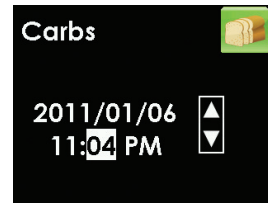
10.1.2 SETTING THE DATE AND TIME FOR AN EVENT

When you enter an event, you must check that the date and time for that event are correct. The default is the current date and time stored in the receiver. The date format is YYYY/MM/DD.

If you change the date or time for any event, it only applies to that event and will not change the current date and time in the receiver.

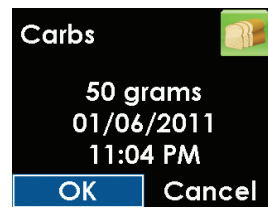
To change the date and time for an event:

1. Press the **RIGHT** button to highlight each value in the date and time.
2. Press the **UP** or **DOWN** button to make any changes, and then press the **RIGHT** button to move to the next value.
3. Press the **SELECT** button after choosing AM or PM.



Carbs setting screen, minutes highlighted

4. Press the **SELECT** button to confirm the entry.

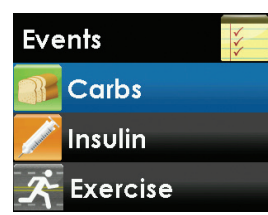


Carbs setting screen, OK highlighted

10.1.3 CARBOHYDRATES

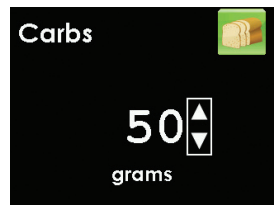
The Carbs event lets you enter the amount of carbohydrates you have taken, up to 250 grams.

1. From the events menu press the **UP** or **DOWN** button to choose “Carbs,” and press the **SELECT** button.



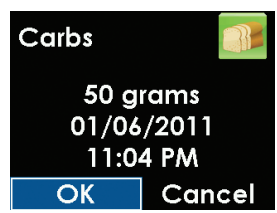
Events menu, Carbs highlighted

2. Press the **UP** or **DOWN** button to enter the carb amount (0-250 grams), and press the **SELECT** button.
   - The number that shows on this screen is the last number you entered or the default amount of 50 grams.



Carbs setting screen, 50 grams selected

3. Check that the date and time for this entry are correct. Press the **SELECT** button to confirm.
4. Press the **LEFT** or **RIGHT** button to choose either “OK” to confirm or “Cancel” to discard this entry, and then press the **SELECT** button. You will return to the Events menu.

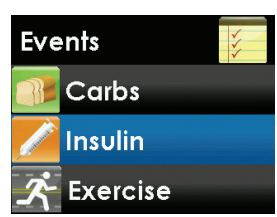


Carbs setting screen, OK highlighted

10.1.4 INSULIN

The Insulin event lets you enter the amount of insulin you have taken, up to 250 units. You can only enter an insulin amount, not the type of insulin.

1. From the Events menu press the **UP** or **DOWN** button to choose “Insulin,” and press the **SELECT** button.

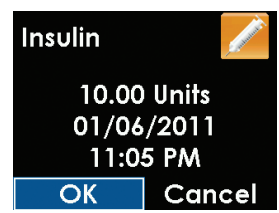


Events menu, Insulin highlighted

2. Press the **UP** or **DOWN** button to enter the insulin amount (0-250 units), and press the **SELECT** button.
   - The number that shows on this screen is the last number you entered or the default amount of 10 units.

Insulin setting screen, 10 units highlighted

3. Check that the date and time for this entry are correct. Press the **SELECT** button to confirm.
4. Press the **LEFT** or **RIGHT** button to choose either “OK” to confirm this entry or “Cancel” to discard this entry, and then press the **SELECT** button. You will return to the Events menu.

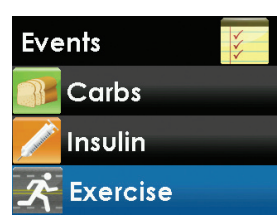


Insulin setting screen, OK highlighted

10.1.5 EXERCISE

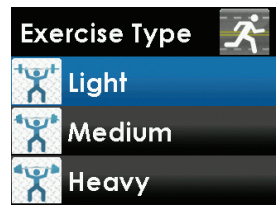
The Exercise event lets you enter intensity (light, medium, or heavy) and duration (up to 360 minutes).

1. From the Events menu press the **UP** or **DOWN** button to choose “Exercise,” and press the **SELECT** button.



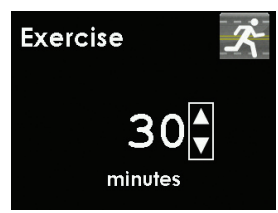
Events menu, Exercise highlighted

2. Press the **UP** or **DOWN** button to choose the exercise intensity level, and press the **SELECT** button.



Exercise Type menu, Light highlighted

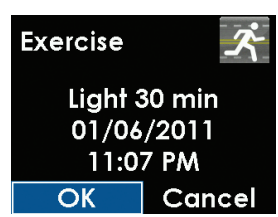
3. Press the **UP** or **DOWN** button to enter the exercise duration (0-360 minutes), and press the **SELECT** button.
   - The number that shows on this screen is the default amount of 30 minutes.



Exercise setting screen, 30 minutes selected

4. Check that the date and time for this entry are correct. Press the **SELECT** button to confirm.

5. Press the **LEFT** or **RIGHT** button to choose either “OK” to confirm this entry or “Cancel” to discard this entry, and then press the **SELECT** button. You will return to the Events menu.

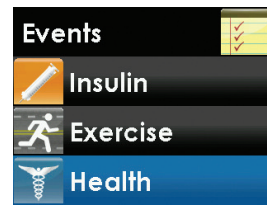


Exercise setting screen, OK highlighted

10.1.6 HEALTH

The Health event lets you enter episodes of illness, stress, high symptoms, low symptoms, cycle (menstrual) or alcohol consumption.

1. From the Events menu press the **UP** or **DOWN** button to choose “Health,” and press the **SELECT** button.

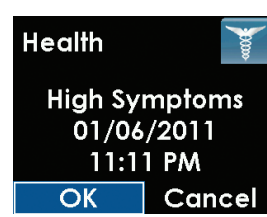


Events menu,
Health highlighted

2. Press the **UP** or **DOWN** button to choose the health event, and press the **SELECT** button.

Health menu,
Illness highlighted

3. Check that the date and time for this entry are correct. Press the **SELECT** button to confirm.
4. Press the **LEFT** or **RIGHT** button to choose either “OK” to confirm this entry or “Cancel” to discard this entry, and then press the **SELECT** button. You will return to the Events menu.



Health setting screen,
OK highlighted

10.2 DEXCOM STUDIO SOFTWARE AND BLINDED MODE

The Dexcom STUDIO software is optional. This software lets you view trends, track patterns and create custom charts to display the glucose trends.

You can use data from downloads and save or print files for users and healthcare professionals to review.

Dexcom STUDIO allows healthcare professionals to blind and unblind receivers. Blinded receivers do not display sensor glucose readings, trends or any glucose alerts or alarms. Blinded receivers record glucose information that the healthcare professional can later download and review using Dexcom STUDIO software.

Healthcare professionals must obtain an authorization code from Dexcom to be able to access this feature. The act of blinding turns on this feature, and unblinding returns the receiver to its normal functions. To obtain a healthcare professional authorization code, please contact Dexcom Technical Support.

For system requirements and more information, see the Dexcom website (www.dexcom.com) or the Dexcom STUDIO Software User's Guide.

10.2.1 ACTIVATING THE BLINDED MODE/CLINICAL FEATURE

WARNING

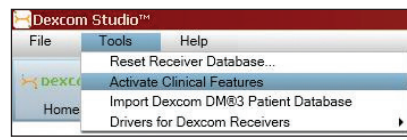
Low/high glucose alerts and the 55 mg/dL low glucose alarm are all disabled when using the Dexcom G4 PLATINUM Professional System in blinded mode and will not alert you when the glucose is low or high. Check blood glucose meter if there are any signs or symptoms of low or high glucose.

To activate clinical features, you need to install the Dexcom STUDIO software from either the CD bundle in the Dexcom G4 PLATINUM Professional Receiver Kit or from the Dexcom website at www.dexcom.com. For system requirements and more information,

see the Dexcom website (www.dexcom.com) or the Dexcom STUDIO Software User's Guide.

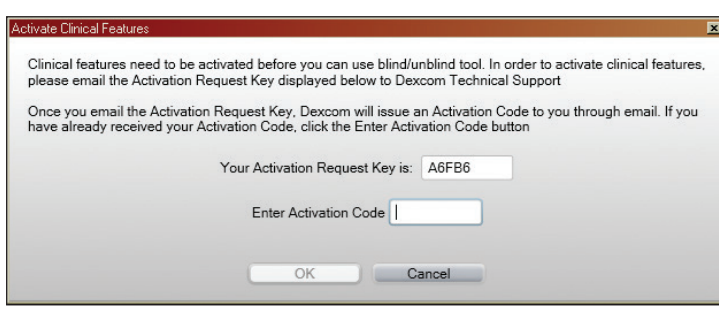
Once the Dexcom STUDIO software has been installed successfully, follow the following instructions to activate the blinded mode/clinical feature:

1. Click "Tools" on the tool bar and select "Activate Clinical Features" from the drop down menu.



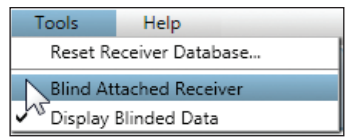
Activate Clinical Features highlighted

2. Dexcom STUDIO software prompts you to contact Dexcom Technical Support and provide them with the Activation Request Key that appears in the Activate Clinical Features pop-up window. Contact Dexcom Technical Support at **1.877.339.2664** or via e-mail at technicalsupport@dexcom.com and provide them your name, your practice name and the Activation Request Key Code. Once you receive an Activation Code from Dexcom Technical Support, enter it in the Activate Clinical Features window. Then click "OK." Clinical features activation is a one-time process, and you will not need to repeat it.


Activate Clinical Features
Clinical features need to be activated before you can use blind/unblind tool. In order to activate clinical features, please email the Activation Request Key displayed below to Dexcom Technical Support
Once you email the Activation Request Key, Dexcom will issue an Activation Code to you through email. If you have already received your Activation Code, click the Enter Activation Code button
Your Activation Request Key is: A6FB6
Enter Activation Code
OK
Cancel

Activate Clinical Features window

The Tools drop down menu now includes an option to Blind/Unblind Attached Receiver, and Display Blinded Data. These options may be useful for healthcare professionals.

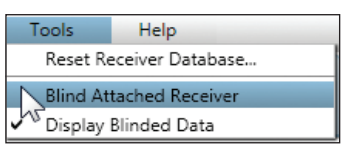


Blind Attached Receiver highlighted

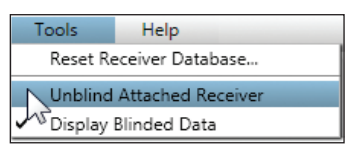
10.2.2 BLINDING THE RECEIVER

NOTE: This feature is for the healthcare professional use only and not for the use of patients.

1. Connect a receiver to the USB port of a computer. This activates the Blind/Unblind Attached Receiver option on the Tools drop down menu if you have previously entered the proper Activation Code.
2. Click on the “Tools” option to either blind or unblind the attached receiver.
3. The option that appears (Blind Attached Receiver or Unblind Attached Receiver) depends on whether the connected receiver is currently blinded or unblinded.



When connected the receiver is currently unblinded



When connected the receiver is currently blinded

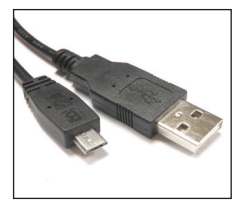
4. Choose “Blind Attached Receiver” or “Unblind Attached Receiver” from the drop down menu. You will be prompted to confirm your selection before the receiver display is updated.

If you change the current blind/unblind setting, an updated group of receiver settings will automatically be downloaded to the software. Some of the downloaded settings may affect the charts/reports currently being displayed in the software.

NOTE: The choice of blinding/unblinding the receiver does not impact the data that is downloaded from the receiver. It does impact whether the data will be visible in charts/reports after downloading.

10.2.3 DOWNLOADING THE RECEIVER

You will need the USB to Micro USB cable provided with the Dexcom G4 PLATINUM Professional System to connect the receiver to the PC.



USB to Micro USB cable

Before downloading the receiver, remove the receiver shield from the receiver to help reduce the spread of contamination.

1. Slide open the USB port cover on the side of the receiver.
2. Plug the Micro USB end of the cable into the receiver USB port.
3. Connect the other end of the cable into any free USB port on the PC.

The software will first try to assign the new receiver download to an existing patient record (using this same receiver). If it does not find a match, the Edit Patient pop-up window will appear where you can create a new patient record for this download. See the Dexcom STUDIO Software User's Guide, Section 5, Patient Management, for editing patient record information.

10.2.4 RESETTING THE RECEIVER FOR MULTIPLE PATIENT USE

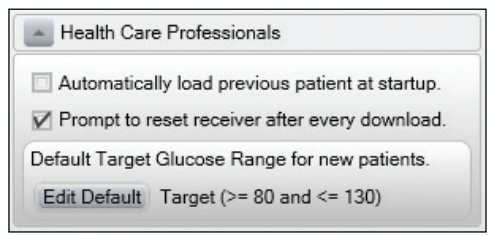
A useful feature for healthcare professionals is to be able to reset the receiver database. Resetting will erase all data from the receiver database, and set the receiver time and date to the Internet time and date. The transmitter ID and blind/unblind settings in the receiver will be preserved. The receiver must be attached to the PC and the Dexcom

STUDIO software must be open to reset the receiver.

Customize what happens each time you open/run the software. **These options are intended for healthcare professionals only.**

You can also choose to automatically be prompted to reset after every download by making this selection in the Options menu.

1. Click on “Health Care Professionals” option and this screen will drop down.


Health Care Professionals
Automatically load previous patient at startup.
Prompt to reset receiver after every download.
Default Target Glucose Range for new patients.
Edit Default
Target (>= 80 and <= 130)

Health Care Professionals

2. Click on “Prompt to reset the receiver after every download.” – select whether to be prompted to reset the receiver after every time you download data.

Resetting will erase all data from the receiver database, set the receiver time and date to the Internet time and date, and set the prior transmitter ID and blind/unblind settings back into the receiver. This is the preferred setting when you are using the Dexcom G4 PLATINUM Professional System for multiple patient use.

For additional information on the Health Care Professional settings in the Dexcom STUDIO software, see the Dexcom STUDIO Software User’s Guide.

NOTE: The receiver will store each patient’s data in its memory. For multiple patient use, it is important that you erase the receiver data memory after each patient use. This will ensure patient privacy with subsequent users.

11

chapter eleven

ENDING A SENSOR SESSION

11

CHAPTER 11: ENDING A SENSOR SESSION

PRECAUTION

Do not discard your transmitter. It is reusable. The same transmitter is used for each session until you have reached the end of the transmitter battery life. When healthcare professionals use one transmitter for multiple patients, the transmitter must be returned to the healthcare professional.

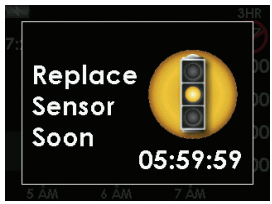
The sensor gives you sensor glucose readings for up to seven days when used in real-time mode. The performance of a sensor has not been tested beyond seven days.

Information for the end of a sensor session:

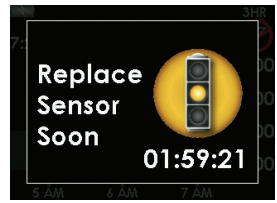
- Do not remove the transmitter from the sensor pod while the pod is attached to the skin.
- Consult the local waste management authorities for instructions to dispose of blood contacting parts (sensor and applicator) if you remove the sensor outside of the healthcare professional office.
- In some cases, the sensor session may end before you have finished a full 7-day period. If this happens, see Chapter 13, Section 13.6, Sensor Shut-Off Troubleshooting.
- **Glucose alerts and alarm do not work after the sensor session ends in both real-time and blinded modes.**

11.1 AUTOMATIC SENSOR SHUT-OFF IN BOTH REAL-TIME AND BLINDED MODES

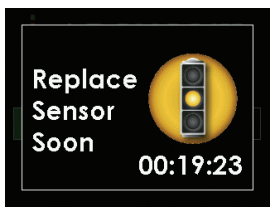
The receiver tells you how much time you have left until the sensor session is complete. The Replace Sensor screen shows at 6 hours, 2 hours and 30 minutes before the 7-day sensor session ends.



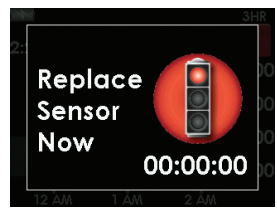
6-hour Replace Sensor



2-hour Replace Sensor



30-minute Replace Sensor

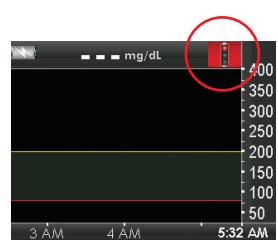


Replace Sensor
end of session

You can set these alerts with the profiles setting (see Chapter 9, Section 9.3.2, Alert Profile Details, “All Other Alerts”). After the 6-hour, 2-hour, and 30-minute reminders, you continue to receive sensor glucose readings. Press **SELECT** to clear these screens. You must remove the sensor after the Replace Sensor Now screen (00:00:00) shows.

Sensor glucose readings do not show on the receiver after the sensor session ends. The trend graphs show that the sensor session has ended with a red stoplight symbol at the top.

You must remove the sensor based on the instructions of your healthcare professional (i.e., the healthcare professional will tell you if you should remove the sensor yourself or return to the healthcare professional’s office to remove the sensor).



Trend graph with
red stoplight in upper right

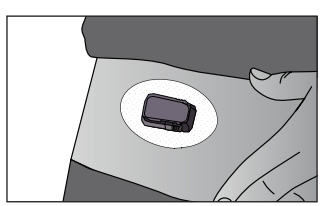
11.2 REMOVING A SENSOR

WARNING

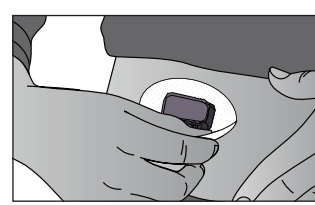
Sensors may fracture on rare occasions. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Seek professional medical help if you have symptoms of infection or inflammation—redness, swelling or pain—at the insertion site. If you experience a broken sensor, please report this to our Technical Support department at **1.877.339.2664 or 1.858.200.0200**.

When you remove the sensor, make sure to pull out the sensor pod while the transmitter is still attached.

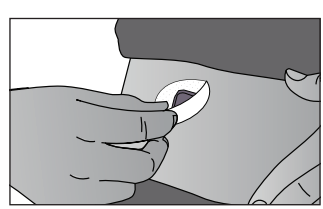
1. Gently peel up the sensor pod adhesive patch from the skin. This will pull out the sensor.



Keep the transmitter in the sensor pod



Peel up the sensor pod adhesive patch



Completely remove the adhesive patch

11.3 TRANSMITTER REMOVAL

WARNING

The transmitter should be cleaned and disinfected after use on each patient. This system may only be used for testing multiple patients when Standard Precautions and the manufacturer's cleaning and disinfection procedures are followed.

PRECAUTION

Do not discard your transmitter. It is reusable. The same transmitter is used for each session until you have reached the end of the transmitter battery life. When healthcare professionals use one transmitter for multiple patients, the transmitter must be returned to the healthcare professional.

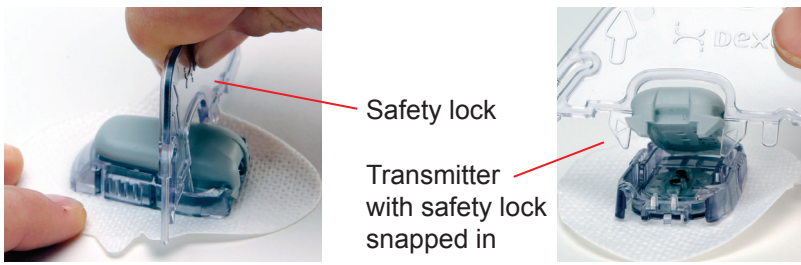
Do not remove the transmitter while the sensor pod is still attached to the body.

After the sensor pod is off the body, you must remove the transmitter to reuse it. Use either of these two transmitter removal methods:

Method 1

The safety lock that you removed from the applicator (see Chapter 6, Section 6.4, Placing the Sensor), can be used as a tool to remove the transmitter.

1. Place the sensor pod/transmitter on a flat surface.
2. Hold the rounded edge of the safety lock.
3. Make sure the jagged edge of the safety lock is facing down, with the arrow pointing up, as shown:



Method 2

Use the fingers to spread out the tabs at the back of the sensor pod (end closest to the sensor pod tab wings). The transmitter will “pop” out of the sensor pod.

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chapter twelve

TAKING CARE OF THE DEXCOM G4 PLATINUM PROFESSIONAL SYSTEM

12

CHAPTER 12: TAKING CARE OF THE DEXCOM G4 PLATINUM PROFESSIONAL SYSTEM

12.1 RECEIVING THE TRANSMITTER AND RECEIVER FROM EACH USER

Before touching the transmitter and receiver used by a patient, make sure the healthcare professional wears personal protective equipment as appropriate (gloves, protective goggles, lab coat, etc.).

12.2 REMOVING THE RECEIVER SHIELD

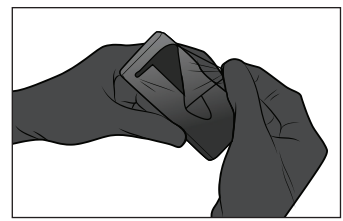
Remove the receiver shield after each patient's use to help reduce the spread of contamination to healthcare professionals and other patients. You will need gloves, Dispatch® Hospital Cleaner Disinfectant Towels with Bleach (any disinfectant wipes containing a bleach solution strength of 6500 parts per million with the EPA registration number 56392-8 may be used), and a clean table or other surface.

1. Wear gloves.

Step 1. Wear gloves

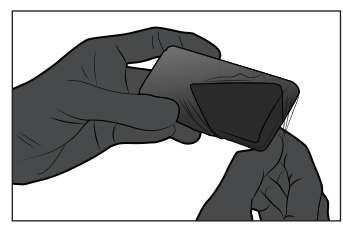
2. **Wipe the shield with the disinfectant wipe to help reduce the likelihood of transferring contaminants from the outside of the shield to the surface of the receiver.** Allow shield to dry on a clean table or surface.
3. Remove and change gloves.

4. Remove and discard the triangle seal that is over the t-shaped slot in the back of the receiver.



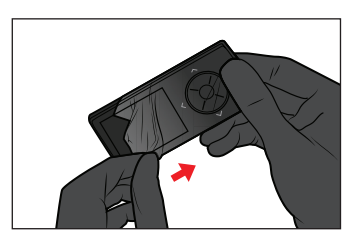
Step 4. Remove triangle seal

5. Hold one corner of the shield near the top of the t-shaped slot. Stretch that corner of the shield off the receiver.



Step 5. Stretch corner of shield off the receiver

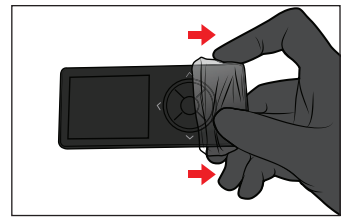
6. Hold the other corner of the shield near the top of the t-shaped slot. Stretch that corner of the shield off the receiver.
7. Peel back the shield, being careful not to touch the outside of the shield or gloved hands to the surface of the receiver.



Step 7. Peel back shield

8. Hold the edge of the shield that is still on the receiver, just above a clean surface.

9. Squeeze the receiver out of the shield (like squeezing toothpaste from a tube) until the receiver is released onto the clean surface. This prevents the outside of the shield from contacting the surface of the receiver.



Step 9. Squeeze receiver out of shield

10. View the shield closely under adequate lighting. Inspect the shield for any signs of damage or deterioration.
    a. If a defect or malfunction of the shield is suspected, the healthcare professional should retain the shield and contact Dexcom Technical Support.
    b. If there is no evidence of defect or malfunction, discard the shield.
11. Remove and change gloves before handling the receiver.
12. View the receiver closely under adequate lighting. Inspect the receiver for any soil or signs of contamination to the receiver.
    a. Discard the receiver if there is any indication of contamination, such as dirt or spots of dried fluid.
    b. Consider whether there has been incorrect shield application or removal that potentially could lead to contamination.
    c. If there is any doubt about contamination, assume it is contaminated and discard the receiver.

Do not clean or disinfect the receiver once the shield is removed. Cleaning and disinfection products could damage the receiver.

NOTE: When removing the shield, peel the receiver shield straight back. While holding the receiver upside down over a clean table or surface, squeeze the receiver out of the shield. Avoid manipulating the receiver shield so that the shield exterior does not come into contact with the receiver and gloves do not transfer material from outside the shield to the receiver.

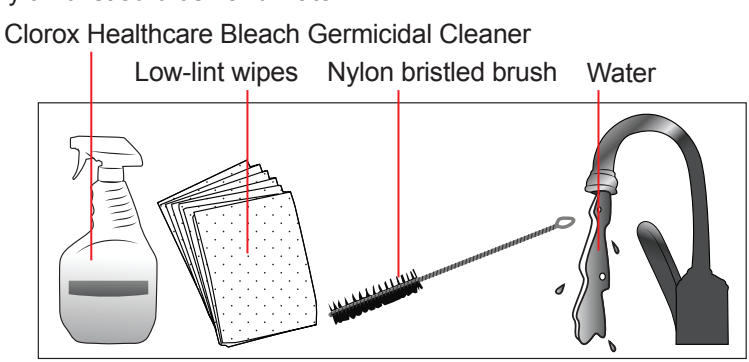
12.3 CLEANING AND DISINFECTION OF THE TRANSMITTER

Dexcom validated 52 cleaning and disinfection cycles. This represents one cleaning and one disinfection cycle per week over twelve months of use, which exceeds the expected transmitter battery life of six months and meets the warranty time of the receiver.

Healthcare professionals must clean and disinfect the transmitter before providing to each user. Clean the transmitter before disinfecting. Use caution when handling products worn or handled by another person. Wear personal protective equipment as appropriate (gloves, protective goggles, lab coat, etc.).

Cleaning

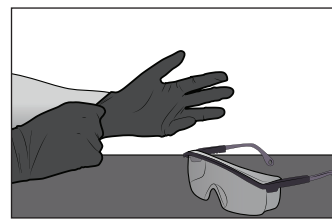
Cleaning removes dirt from the surface of the transmitter. It does not kill bacteria or viruses. The transmitter should be cleaned whenever it is visibly dirty and between each use. In addition to the minimum recommendations to clean between each use, the transmitter can be cleaned whenever it is visibly dirty up to 26 times over the six month use life. You will need Clorox Healthcare® Bleach Germicidal Cleaner (formerly "Dispatch®"; any disinfectant product in a spray bottle containing a bleach solution strength of 6500 parts per million with the EPA registration number 56392-7 may be used), low-lint cloths or wipes, a nylon bristled brush and water.



Components to clean the transmitter

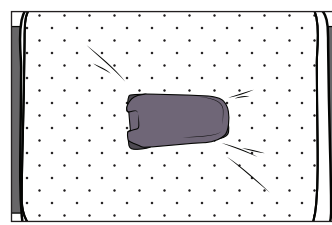
Cleaning the Transmitter

1. Wear clean gloves and goggles.



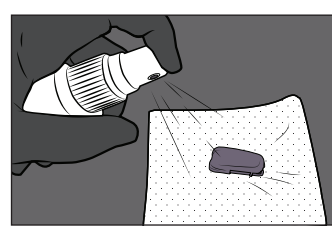
Step 1. Wear gloves and goggles

2. Prepare a soaking container by adding enough Clorox Healthcare Bleach Germicidal Cleaner solution to submerge a transmitter.
3. Place the transmitter with the contact (metal circles) side down on an absorbent wipe or clean surface.



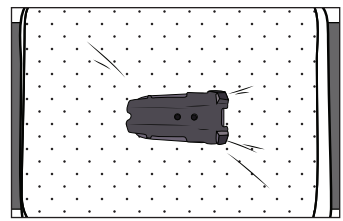
Step 3. Transmitter with contact side down on absorbent wipe

4. Hold the Clorox Healthcare Bleach Germicidal Cleaner spray bottle 6-8 inches from unit, and dispense two sprays onto the top surface.



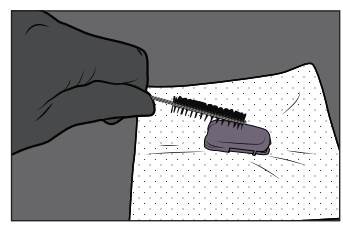
Step 4. Spray transmitter

5. Flip the transmitter over to expose the contacts (metal circles).



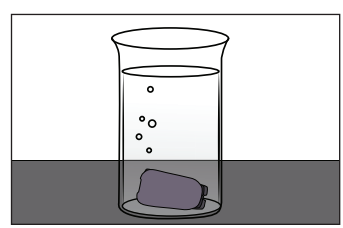
Step 5. Transmitter with contact side up on absorbent wipe

6. Hold the Clorox Healthcare Bleach Germicidal Cleaner spray bottle 6-8 inches from unit, and dispense two sprays onto the side with the contacts (metal circles).
7. Using a nylon brush, scrub the transmitter on all sides for thirty seconds.



Step 7. Scrub transmitter using nylon brush

8. Place the transmitter in the Clorox Healthcare Bleach Germicidal Cleaner spray solution for one minute.

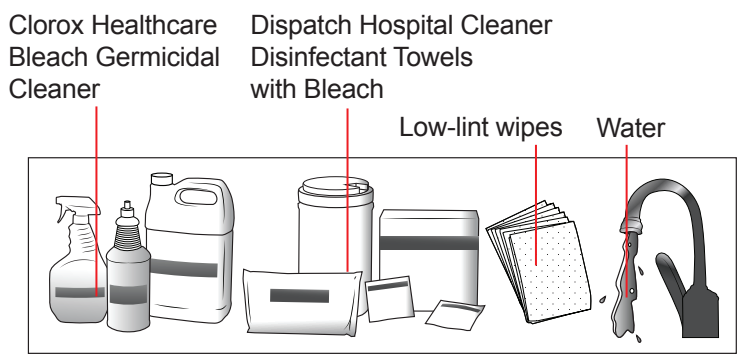


Step 8. Place transmitter in solution

9. Remove the transmitter and rinse it under flowing tap water for ten seconds.
10. Wipe the transmitter with a cloth until it is completely dry.

Disinfection

Disinfection removes and destroys microorganisms and pathogens from the transmitter's surface. Disinfect the transmitter between each user and whenever you suspect that blood or body fluid has come in contact with the surface of the device. You will need Clorox Healthcare Bleach Germicidal Cleaner (formerly, "Dispatch;" any disinfectant product containing a bleach solution strength of 6500 parts per million with the EPA registration number 56392-7 may be used), Dispatch Hospital Cleaner Disinfectant Towels with Bleach (any disinfectant wipes containing a bleach solution strength of 6500 parts per million with the EPA registration number 56392-8 may be used), low-lint cloths or wipes, and water (products needed are illustrated in the next image). Clean the transmitter before disinfecting.



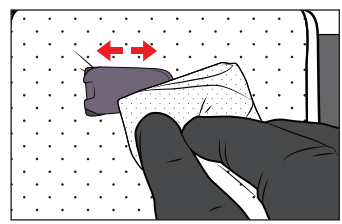
Components to disinfect the transmitter

Disinfecting the Transmitter

1. Wear clean gloves and goggles.

Step 1. Wear gloves and goggles

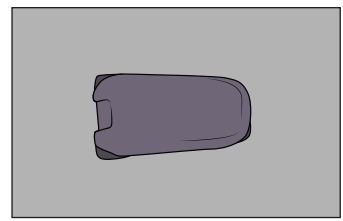
2. Prepare a soaking container by adding enough Clorox Healthcare Bleach Germicidal Cleaner to submerge a transmitter.
3. Place the transmitter with the contact (metal circles) side down on an absorbent wipe or clean surface.
4. Remove a pre-saturated Dispatch Hospital Cleaner Disinfectant Towel with Bleach from its packaging.
5. Fold the Dispatch Hospital Cleaner Disinfectant Towel with Bleach into a 2 x 2 inch square.
6. Wipe all surfaces of the transmitter by passing over the transmitter surface in one direction and then back in the opposite direction (back and forth means two passes).



Step 6. Wipe transmitter back and forth

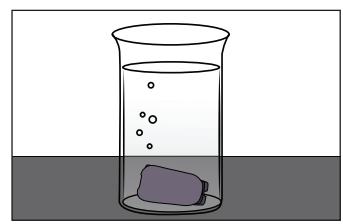
7. Turn over the Dispatch Hospital Cleaner Disinfectant Towel with Bleach to use a clean side for a second back and forth wipe.
8. Refold the Dispatch Hospital Cleaner Disinfectant Towel with Bleach to use a clean side for a third back and forth wipe.
9. Turn over the Dispatch Hospital Cleaner Disinfectant Towel with Bleach to use a clean side for a fourth back and forth wipe.
10. Keep track to be sure you wiped four times back and forth for a total of eight passes and that all transmitter surfaces are covered with disinfectant.

11. Place the transmitter on a clean non-porous surface and allow the disinfectant to contact it for one minute.



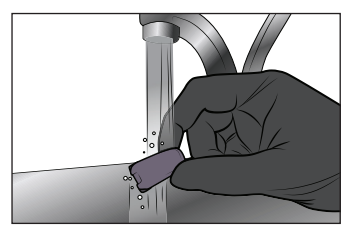
Step 11. Place transmitter on clean surface

12. Place the transmitter in the Clorox Healthcare Bleach Germicidal Cleaner spray solution for one minute.



Step 12. Place transmitter in solution

13. Remove the transmitter and rinse it under flowing tap water for ten seconds.



Step 13. Rinse transmitter under flowing water

14. Wipe the transmitter with a low lint, absorbent cloth until it is completely dry.

After cleaning and disinfection, remove and discard gloves, and wash hands thoroughly with soap and water.

Clorox Healthcare Bleach Germicidal Cleaner (EPA registration number 56392-7) and Dispatch Hospital Cleaner Disinfectant Towels with Bleach

(EPA registration number 56392-8) may be purchased from medical office supply providers. For current suppliers, see the Clorox® Company at www.cloroxprofessional.com.

Stop using the transmitter and contact Dexcom Technical Support if signs of deterioration are noted. Signs of deterioration include corrosion or discoloration on the metal transmitter contacts, pitting of the transmitter's gray epoxy surface, reduced legibility of the text on the bottom of the transmitter, or any other visual changes to the transmitter. Repeated sensor failures (see Chapter 13, Section 13.6.1, Sensor Failed screen) or glucose reading errors (??? symbol, see Chapter 8, Section 8.3, Glucose Status Area Symbols in Both Real-Time and Blinded Modes) that occur with multiple sensors could indicate deterioration of the transmitter.

TECHNICAL SUPPORT

For Dexcom product questions and troubleshooting issues.

Dexcom Technical Support Phone Numbers:

1.877.339.2664 or 1.858.200.0200

(24 hours, 7 days a week)

Dexcom Technical Support E-mail:

TechSupport@dexcom.com

Dexcom Technical Support Fax:

1.877.633.9266

References:

"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010), http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm.

"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010), http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html.

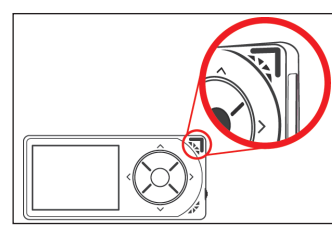
12.4 USING THE RECEIVER SHIELD

Healthcare professionals must apply a shield and its components to the receiver before providing to each user. Use caution when handling products worn or handled by another person. Wear personal protective equipment as appropriate (gloves, protective goggles, lab coat, etc.). Use only legally marketed Dexcom G4 PLATINUM Professional Receiver Shields (manufactured by Seal Shield™ specifically for the use of the Dexcom G4 PLATINUM Receiver).

The shield helps prevent microorganisms and pathogens from reaching the receiver's surface. Replacing the receiver shield between each use helps reduce the spread of contamination between users and healthcare practitioners.

The receiver volume may be reduced if the acoustic spacers are not in place. If the acoustic spacer is not in place, the user should return the receiver to the healthcare professional.

1. Wash hands and put on sterile gloves. Peel acoustic spacer from paper backing and secure on upper speaker edge.

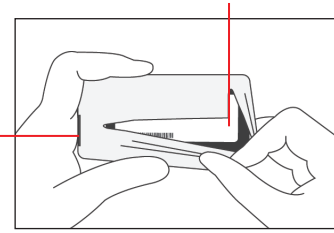


Acoustic spacer in upper right of receiver

Opening back of receiver

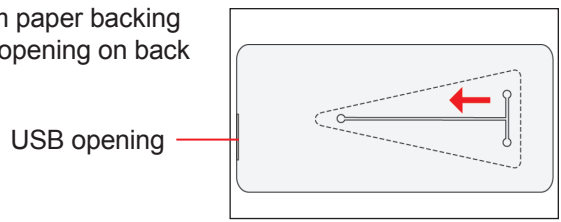
2. Note location of USB opening on receiver shield. Stretch receiver shield over receiver.

USB opening lined up with USB port

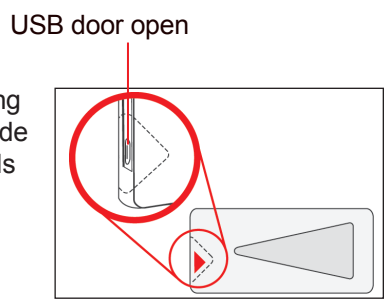


Stretch receiver shield over receiver

3. Peel triangle seal from paper backing and secure seal over opening on back of receiver.



Triangle seal over shield opening



4. Peel 1 square seal from paper backing and secure seal over USB door on side of receiver. Save additional USB seals for recharging.

Square seal over USB port

NOTE: The receiver shield is not waterproof and does not protect the receiver from water or liquids.

12.5 MAINTENANCE

Transmitter

- Keep the transmitter protected when not in use.

Receiver

- Do not spill fluid on the receiver or submerge the receiver in liquid.
- Keep the receiver protected.
- Charge the receiver when the battery gets low, optimally before each new patient use.

Accessories

- Insert cables only as directed. Do not force cables in place.
- Look at cables for signs of wear and tear.
- Only use Dexcom-supplied parts (including cables and chargers). Use of non-Dexcom supplied parts may affect safety and performance.

There is no repair service available for the Dexcom G4 PLATINUM Professional CGM System. If you experience problems with the system contact Dexcom Technical Support (see Chapter 15, User Assistance).

12.6 STORAGE

Sensor

- Keep the sensor in its sterile packaging until you are ready to use it.
- Do not insert sensors past the expiration date. The expiration date format is YYYY-MM-DD. Insert sensors on or before the end of the calendar day printed on the sensor package label.
- Store at temperatures between 36° F - 77° F. Storing outside this temperature may result in reduced sensor response to glucose and may cause inaccurate CGM readings. You may store the sensors in the refrigerator if it is within this temperature range. Sensors should not be stored in a freezer.
- Store at humidity levels between 15% - 85% relative humidity.

Transmitter

- Keep the transmitter protected when not in use.
- Store at temperatures between 32° F - 113° F.
- Store at humidity levels between 10% - 95% relative humidity.

Receiver

- Keep the receiver protected when not in use.
- Fully charge the battery before storing for over 3 months.
- Store at temperatures between 32° F - 113° F.

- Store at humidity levels between 10% - 95% relative humidity.

12.7 PRODUCT DISPOSAL

Consult the local waste management authorities for instructions to dispose of devices containing electronic waste (transmitter and receiver) and blood contacting parts (sensor and applicator).

chapter thirteen

TROUBLESHOOTING

13

CHAPTER 13: TROUBLESHOOTING

This chapter provides helpful tips and instructions to fix issues you may have while using the Dexcom G4 PLATINUM Professional CGM System.

If any of the troubleshooting steps in this chapter do not fix the issue, contact Dexcom Technical Support (see Chapter 15, User Assistance).

13.1 SENSOR INSERTION TROUBLESHOOTING

Sensor insertion difficulties

• I am having trouble taking out the safety lock:

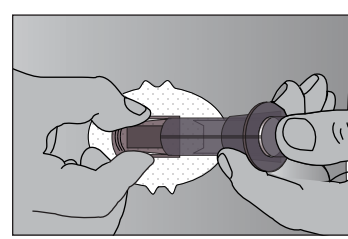
- Make sure to pull the safety lock straight out away from the body. Use the arrows on the safety lock as a guide.

• I am not able to pull the collar up:

- Make sure the white plunger is completely pressed down before pulling the collar up.
- Use force when pulling the collar up.

• I am not able to remove the applicator barrel from the sensor pod:

- Make sure the collar is pulled all the way up. When pulling the collar up you should hear 2 “clicks.” You may need to use extra force to pull the collar as close to the top of the applicator as possible.
- Make sure the transmitter latch is flat against the adhesive on the body before squeezing the release tabs.
- Use force when squeezing the ribbed release tabs on the sides of the sensor pod.
- Lift the applicator in a curving movement away from the body.



Release the applicator barrel

- **I am not able to remove the transmitter latch:**
  - Hold the sensor pod with one hand and twist the transmitter latch with the other hand to remove it.
  - Do not try to snap it straight off.

Sensor pod is not sticking long enough

- Make sure the skin is clean, clear of any cream or lotion, and completely dry before you insert the sensor.
- Shave the skin before you insert the sensor if hair is preventing the sensor pod from sticking.
- You may use medical tape (such as Blenderm, Tegaderm, Smith & Nephew IV3000, 3M tape) over the white adhesive patch of the sensor pod, but do not place the tape over the transmitter or the plastic parts of the sensor pod.

13.2 CALIBRATION TROUBLESHOOTING

Calibration prompts may show during the sensor session. Review the following troubleshooting tips for calibration.

- Do not calibrate if the out of range symbol shows in the status area.
- Do not calibrate if the glucose reading error symbol shows in the status area.
- Do not calibrate if the blood glucose value is below 40 or above 400 mg/dL.
- Before you take a blood glucose value for calibration, wash hands, make sure the glucose test strips have been stored properly and are not expired and make sure that the meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions that came with the meter or test strips.
- Make sure you have not taken any medications containing acetaminophen (such as Tylenol).

- See Chapter 7, Calibrating the Dexcom G4 PLATINUM Professional System, for further information.

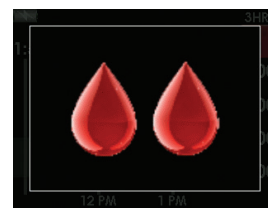
13.2.1 TYPES OF CALIBRATION PROMPTS

This section describes the three calibration symbols. The next section describes what to do when you see one of these symbols.

Startup calibration prompt

This prompt means the receiver's 2-hour startup period is complete. You need to enter two blood glucose values to calibrate the system.

The receiver shows the 2-hour startup calibration prompt screen every 15 minutes until the receiver accepts the blood glucose values.

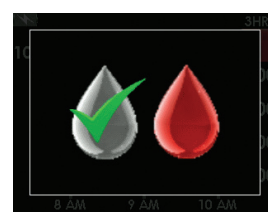


Startup calibration prompt

Additional startup calibration prompt

This prompt means you need to enter one more blood glucose value to calibrate the system.

The receiver shows the additional startup calibration prompt screen every 15 minutes until the receiver accepts the blood glucose value.



Additional startup calibration prompt

Calibration prompt

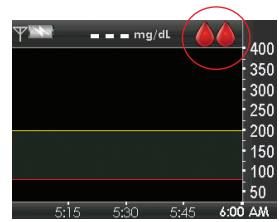
This prompt means you need to enter one blood glucose value. It shows when it is time for the 12-hour calibration update or any other time you need to calibrate.

The receiver shows this prompt screen every 15 minutes until the receiver accepts the blood glucose value.

Calibration prompt

13.2.2 WHAT TO DO FOR CALIBRATION PROMPTS

1. When you see a calibration prompt, press the **SELECT** button to clear the prompt.
2. Check the status area at the top of the screen.
   a. If the startup calibration symbol shows, take 2 more blood glucose values and enter them into the receiver.
   b. If the additional startup calibration symbol shows, take 1 more blood glucose value and enter it into the receiver.
   c. If the calibration needed symbol shows, take 1 more blood glucose value and enter it into the receiver.



Prompt in status area

13.3 CALIBRATION ERROR TROUBLESHOOTING

This screen means you recently entered a calibration blood glucose value, and the sensor is having trouble calibrating. If you press the **SELECT** button to clear this screen, this symbol shows in the status area.

Wait 15 minutes calibration error screen

If you see this screen, wait 15 minutes and then enter 1 more calibration blood glucose value. Wait 15 more minutes. If this error screen still shows, enter 1 more blood glucose value. Wait another 15 minutes. If this error screen still shows, the sensor needs to be replaced.

This screen also means you recently entered a calibration blood glucose value and the sensor is having trouble calibrating. If you press the

SELECT button to clear the screen, this symbol shows in the status area.

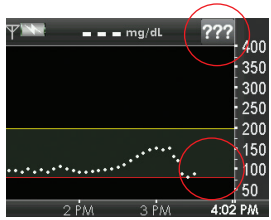
If you see this screen, wait at least 1 hour and then enter 1 more calibration blood glucose value. Wait 15 minutes. If this error screen still shows, enter 1 more blood glucose value. Wait another 15 minutes. If this error screen still shows, the sensor needs to be replaced.

Wait 1 hour calibration error screen

13.4 SYSTEM GLUCOSE ERROR

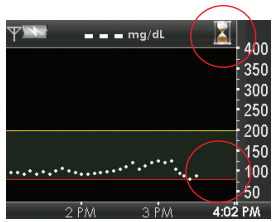
The system may tell you that it cannot provide a sensor glucose reading. When this happens you will see either the glucose reading error symbol ??? or the wait symbol in the status area. These symbols mean the receiver does not understand the sensor signal temporarily. These symbols are related to the sensor only.

Wait for more prompts, and **do not enter** any blood glucose values when you see these symbols. The system will not use a blood glucose value for calibration when these symbols show (see Chapter 8, Section 8.3, Glucose Status Area Symbols in Both Real-Time and Blinded Modes).



No glucose data (???) in real-time mode

No glucose data (???) in blinded mode



No glucose data ( ) in real-time mode

No glucose data ( ) in blinded mode

Often, the system can correct the problem and continue providing or recording sensor glucose readings. If it has been at least 3 hours since the last sensor glucose reading, contact Technical Support (see Chapter 15, User Assistance).

If you see these system glucose error icons often, follow these troubleshooting tips before inserting another sensor:

- Make sure the sensor is not expired.
- Make sure the sensor pod is not dislodged or peeling up.
- Make sure the transmitter is snapped in completely.
- Make sure nothing is rubbing the sensor pod (i.e. clothing, seat belts, etc.).
- Make sure you selected a good insertion site (see Chapter 6, Section 6.3, Choosing an Insertion Site).
- Make sure the insertion site is clean and dry before sensor insertion.

13.5 SENSOR INACCURACIES IN REAL-TIME MODE

Inaccuracies are usually related to the sensor only and not the receiver or transmitter. The sensor glucose readings are meant to be used for trending purposes only. The blood glucose meter and sensor measure the glucose from two different types of body fluids: blood and interstitial

fluid. Therefore, the readings from the blood glucose meter readings and sensor may not match.

WARNING

Calibrate at least once every 12 hours. Calibrating less often than every 12 hours might cause sensor glucose readings to be inaccurate, and you might miss a low or high blood glucose value.

PRECAUTION

To calibrate the system, enter the exact blood glucose value that your blood glucose meter displays within 5 minutes of a carefully performed blood glucose measurement. Entering incorrect blood glucose values or blood glucose values from more than 5 minutes before entry might affect sensor performance, and you might miss a low or high blood glucose value.

If the difference between the sensor glucose reading and blood glucose value is greater than 20% of the blood glucose value for sensor glucose readings > 80 mg/dL or greater than 20 points for sensor glucose readings < 80 mg/dL, wash hands and take another blood glucose measurement. If the difference between this second blood glucose measurement and the sensor is still greater than 20% for sensor glucose readings > 80 mg/dL or greater than 20 points for sensor glucose readings < 80 mg/dL, recalibrate the sensor using the second blood glucose value. The sensor glucose reading will correct over the next 15 minutes. If you see differences between the sensor glucose readings and blood glucose values outside of this acceptable range, follow the troubleshooting tips below before inserting another sensor:

- Make sure the sensor is not expired.
- Make sure you do not calibrate when the ??? or are shown.
- Do not use alternative blood glucose site testing (blood from the palm or forearm, etc.) for calibration as alternative site readings may be different than those from a blood glucose value. Use a blood glucose value only from the fingers for calibration.
- Use only blood glucose values between 40-400 mg/dL for calibration. If one or more of the values is outside of this range, the receiver will not calibrate.
- Use the same meter you routinely use to measure the blood glucose to calibrate. Do not switch the meter in the middle of a sensor session. Blood glucose meter and strip accuracy vary between blood glucose meter brands.
- Before taking a blood glucose measurement for calibration, wash hands, make sure the glucose test strips have been stored properly and are not expired and make sure that the meter is properly coded (if required). Carefully apply the blood sample to the test strip following the instructions provided with the meter or test strips.
- Make sure you are using the blood glucose meter following the manufacturer's instructions to get accurate blood glucose values for calibration.
- Make sure you have not taken any medications containing acetaminophen (such as Tylenol) to ensure you are getting accurate blood glucose values for calibration.

13.6 SENSOR SHUT-OFF TROUBLESHOOTING

In some cases the sensor session may stop or need to be stopped before the end of a full 7-day period. You must remove the sensor and contact your healthcare professional.

13.6.1 EARLY SENSOR SHUT-OFF – SENSOR FAILURE

The receiver may detect issues with the sensor where it cannot determine the sensor glucose reading. The sensor session ends and the receiver shows the “Sensor Failed” screen. If you see this screen, it means the CGM session has ended. Press the **SELECT** button to clear this screen.

Sensor Failed screen

Contact your healthcare professional. You may need to remove the sensor yourself or your healthcare professional might help you remove it and insert a new sensor, if appropriate.

To help improve future sensor performance:

- Make sure the sensor is not expired.
- Make sure the transmitter is snapped in.
- Make sure the sensor pod is not dislodged or peeling up.
- Make sure nothing is rubbing the sensor pod (i.e. clothing, seat belts, etc.).
- Make sure you have selected a good insertion site (see Chapter 6, Section 6.3, Choosing an Insertion Site).
- Make sure the insertion site is clean and dry prior to sensor insertion.

13.6.2 MANUAL SENSOR SHUT-OFF – “STOP SENSOR”

There may be times that the user or healthcare professional will want to stop the sensor session before the end of the seven days. Some of these times may include removing the sensor early due to:

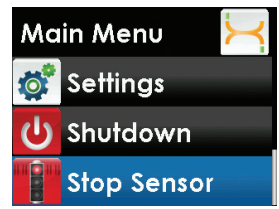
- Calibration issues that cannot be resolved
- ??? symbol that does not resolve
- Sensor adhesion issues

- Lifestyle needs

When you are in an active sensor session, you will see the “Stop Sensor” option but not the “Start Sensor” option on the Main Menu.

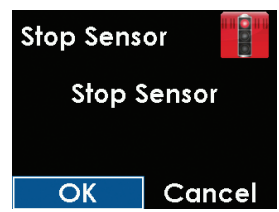
When you are not in an active sensor session, you will see the “Start Sensor” option but not the “Stop Sensor” option on the Main Menu.

Stop the sensor session if you remove the sensor before the end of the full 7-day period.



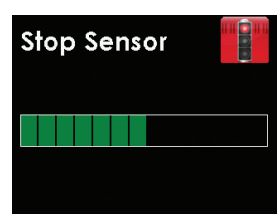
Main Menu,
Stop Sensor highlighted

1. To end the sensor session, select “Stop Sensor” from the Main Menu.
2. Press the **SELECT** button with “OK” highlighted to confirm.



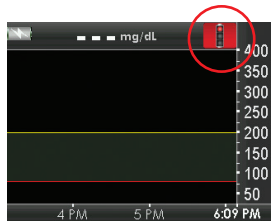
Stop Sensor screen,
OK highlighted

3. The Stop Sensor “thinking” screen will show to let you know the sensor session is stopping.

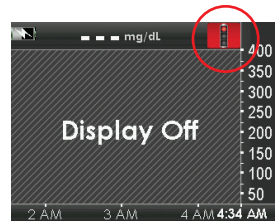


Stop Sensor
“thinking” screen

4. Once the session has stopped, a red stoplight symbol ( ) shows in the upper right of the trend graph.



Trend graph with red stoplight in upper right in real-time mode



Trend graph with red stoplight in upper right in blinded mode

13.7 BATTERY AND CHARGER TROUBLESHOOTING

Only use the Dexcom cable and battery charger to charge the receiver.

A full charge can take up to 5 hours and will last about 3 days, depending on how often you turn on the receiver, use the alerts, and enter events.

If the receiver does not show the battery charging symbol when plugged into the charger, make sure that both ends of the USB cable are fully inserted into the receiver port and wall charger or computer.

If the battery drains and is not charged for a few weeks it may not turn on. If the receiver does not turn on, try to charge it (see Chapter 4, Section 4.1, Charging the Receiver Battery). If the receiver does not charge, contact Dexcom Technical Support and tell them that you are using a receiver with a shield.

13.8 RECEIVER AND TRANSMITTER COMMUNICATION TROUBLESHOOTING

13.8.1 SYSTEM RECOVERY CHECK

This screen means the system found an error that it was able to fix.

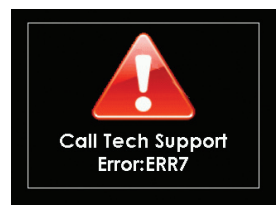
Press the **SELECT** button to clear this display, and continue the sensor session.

System Check screen

13.8.2 RECEIVER ERROR CODE

This screen shows an error code that means the receiver may not be working properly. Write down the error code and contact Dexcom Technical Support (see Chapter 15, User Assistance). Continue to check the blood glucose value using the blood glucose meter.

No alert sound or vibration will warn you that you are no longer getting sensor glucose readings.



Receiver Error Code screen

13.8.3 TRANSMITTER LOW BATTERY

This screen shows when the transmitter nears the end of its battery life (see Chapter 1, Section 1.4, Transmitter Overview). It will first show when there is about 1 week of battery life left. When the transmitter battery drains low enough, the transmitter and receiver will stop communicating. Replace the transmitter as soon as possible after you see this screen. Contact Dexcom Sales Support (see Chapter 15, User Assistance) to order a new transmitter.

Transmitter Low Battery screen

13.8.4 TRANSMITTER FAILED ERROR CODE

This screen means that the transmitter is not working. If you get this alert during a sensor session, the sensor session automatically stops. Contact Dexcom Technical Support (see Chapter 15, User Assistance). Continue to check the blood glucose value using the blood glucose meter.

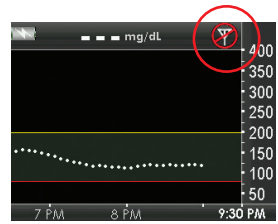
Transmitter Failed screen

13.9 OUT OF RANGE/NO ANTENNA

PRECAUTION

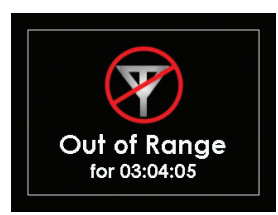
The transmission range from the transmitter to the receiver is up to 20 feet without obstruction. Wireless communication does not work well through water so the range is much less if you are in a pool, bathtub, or on a water bed, etc. Types of obstruction differ and have not been tested. If your transmitter and receiver are farther than 20 feet apart or are separated by an obstruction, they might not communicate or the communication distance may be shorter and you might miss a low or high blood glucose value.

This screen means the receiver and transmitter are not communicating and you are not getting sensor glucose readings.



Out of range symbol appears in upper right of trend graph

- The receiver and transmitter only communicate when you are in an active sensor session.
- Each time you start a new sensor session, wait 10 minutes for the receiver and transmitter to start communicating.
- You may sometimes experience loss of communication for 10 minutes at a time. This is normal.
- If you see the out of range symbol in the status area for more than 10 minutes, move the receiver and transmitter within 20 feet of each other without obstruction. Wait 10 minutes and communication should be restored.
- You must enter the transmitter ID correctly into the receiver to receive sensor glucose readings (see Chapter 5, Section 5.2, The Settings Menu). Make sure you have removed the sensor and stopped the sensor session before checking or changing the transmitter ID. “Transmitter ID” will not appear as an option on the Settings menu during a sensor session.
- The out of range alert is an advanced feature that can be turned on when appropriate. If this advanced feature is turned on, it will alert when the receiver and transmitter are not communicating for a set amount of time depending on the profile settings.



Out of Range alert screen

If you are still having trouble getting system readings, contact Dexcom Technical Support (see Chapter 15, User Assistance).

13.10 ALERTS ARE NOT WORKING

WARNING

Low/high glucose alerts and the 55 mg/dL low glucose alarm are all disabled when using the Dexcom G4 PLATINUM Professional System in blinded mode and will not alert you when the glucose is low or high. Check blood glucose meter if there are any signs or symptoms of low or high glucose.

1. Make sure you have not turned off the sound and/or vibrations for the alerts. Chapter 9, Section 9.1, Setting the Alerts in Real-Time Mode explains how to change these alert options.
2. Check that you have turned on and set the level for the advanced alerts (see Chapter 9, Section 9.2, Advanced Alerts).
3. Remember, the first alert is vibrate only. See Chapter 18, Appendix I, Receiver Alerts, Alarm and Prompts sequence tables for how the alerts, alarm and prompts work.

If the receiver gets wet, dropped, or the acoustic spacer moves, make sure the speaker and vibrations still work. You can do this with the Try It option in the profiles menu (see Chapter 9, Section 9.3.1, Alert Profile Options).

PRECAUTIONS

- Return the receiver to the healthcare professional if the acoustic spacer moves away from the upper right corner. The entire receiver shield must be discarded and replaced. The spacer allows the receiver speaker

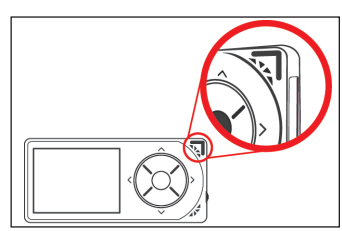
(continued on next page)

PRECAUTIONS (continued from page before)

to work properly when the shield is in place. If the spacer moves and the receiver speaker volume is low, you might miss alerts or alarms.

- Inspect the receiver shield, seals and spacer for tears or other damage or defects before you place the components on the receiver. Do not use any parts of the receiver shield pack that are damaged or defective. If the receiver shield, seals and spacer are torn, damaged or otherwise defective after giving to the patient, the patient should return the receiver to the healthcare professional for a replacement. The damaged or defective receiver shield should not be taken off by the patient. If a defect or malfunction is suspected, the healthcare professional should retain the shield and contact Dexcom Technical Support. The shield helps protect the user and healthcare professionals from contamination and allows the receiver to function properly.

If a patient returns a receiver because the spacer is torn, damaged or defective, discard the shield, seal and spacer and replace with a new shield, seal and spacer.



Acoustic spacer in upper right of receiver

chapter fourteen

TECHNICAL INFORMATION

14

CHAPTER 14: TECHNICAL INFORMATION

14.1 DEVICE PERFORMANCE CHARACTERISTICS

NOTE: We recommend that you review the information in this chapter to understand how well the Dexcom G4 PLATINUM Professional System performs. The Dexcom G4 PLATINUM Professional System is the same as the Dexcom G4 PLATINUM System with the addition of the receiver shield. Therefore, the Dexcom G4 PLATINUM System clinical study is applicable to this system. The Dexcom G4 PLATINUM Professional System uses a real-time algorithm and does not retrospectively process sensor glucose data.

The Dexcom G4 PLATINUM System (the System) uses a glucose sensor to continuously measure and monitor your glucose levels. The sensor is “calibrated” using a commercially available blood glucose meter; and once calibrated the System reports sensor glucose readings up to every 5 minutes. The System was evaluated in a clinical study in which System readings were compared to blood glucose values to assess its performance and how well the System readings compare to a laboratory test method that measures blood glucose values. Additionally, patients performed self-monitoring blood glucose meter tests at home to assess the System performance in real use environment.

Although the performance characteristics of the System are presented in the following, there is no commonly accepted statistical approach for capturing performance of continuous glucose monitors (CGMs), such as the Dexcom G4 PLATINUM System.

Clinical Study Overview

The System performance was evaluated in a prospective clinical study; 72 participants were enrolled. All participants had Type 1 or Type 2 diabetes mellitus, and required insulin or oral medication to manage their diabetes. About 83% of participants had Type 1 diabetes and about 17% of participants had Type 2 diabetes. The study included subjects greater than 18 years of age.

Participants used the System for seven days. Thirty-six participants each wore 2 sensors. Sensors were calibrated approximately once every 12 hours, using the self-monitoring blood glucose (SMBG) meter values obtained from the LifeScan® OneTouch® Ultra® 2 meter. Throughout the 7-day wear period, the sensor was calibrated with an average of 2 fingersticks per day (approximately once every 12 hours).

All subjects were evaluated in a controlled clinic environment on Day 1, Day 4, and Day 7 of the 7-day wear period. While using the System in the clinic, participants had their blood glucose measured every 15 minutes with a reliable laboratory method, the Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer. This instrument is referred to as the "YSI." Readings from the System were reported every 5 minutes and paired with YSI values in order to characterize how well the System readings agreed with laboratory standard blood glucose results. The remainder of the study took place at home, the System performance was also paired with the comparative LifeScan OneTouch Ultra 2 meter results, and that is referred to as the 'SMBG'.

Agreement

Agreement between the System and blood glucose values is characterized using paired System and YSI values. The System and YSI results were compared by pairing the YSI blood glucose value to a System glucose reading that occurred immediately after the YSI was collected.

The agreement of the System to blood glucose value was assessed by calculating the percentage of System readings that were within 15%, 20%, 30%, 40% and greater than 40% of the YSI values. For readings less than or equal to 80 mg/dL (4.4 mmol/L) the absolute difference in mg/dL (mmol/L) between the two glucose results was calculated. For values greater than 80 mg/dL (4.4 mmol/L) the absolute percent difference (%) from the YSI values was calculated. The percentages of total readings within 15 mg/dL (0.8 mmol/L) or 15%, 20 mg/dL (1.1 mmol/L) or 20%, 30 mg/dL (1.7 mmol/L) or 30%, 40 mg/dL (2.2 mmol/L) or 40% or greater than 40 mg/dL (2.2 mmol/L) or 40% were then calculated in Table 1-A and Table 1-B.

The total number of data pairs considered in this analysis was 9152. Of these, eighty-two percent (82%) of the System readings fall within ±20 mg/dL (1.1 mmol/L) of the YSI blood glucose values (≤ 80 mg/dL or 4.4 mmol/L) and within ±20% of YSI blood glucose values (> 80 mg/dL or 4.4 mmol/L).

Table 1-A. System Agreement to YSI within CGM Glucose Ranges

CGM Glucose Range mg/dL (mmol/L)	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent within 40/40% YSI	Percent Greater than 40/40% YSI
Overall	9152	71%	82%	92%	97%	3%
40-60 (2.2-3.3)	512	67%	78%	88%	94%	6%
61-80 (3.4-4.4)	781	73%	85%	94%	98%	2%
81-180 (4.5-10.0)	3853	67%	78%	91%	97%	3%
181-300 (10.1-16.7)	2784	72%	84%	93%	96%	4%
301-350 (16.7-19.4)	775	82%	91%	97%	98%	2%
351-400 (19.4-22.2)	447	74%	84%	91%	95%	5%

NOTE: CGM readings are within 40-400 mg/dL (2.2-22.2 mmol/L), inclusive.

Table 1-A is categorized within CGM glucose ranges. When you see a CGM reading on your receiver, this table shows you how likely that reading matches your blood glucose level (measured by YSI in the study). For example, if your CGM reads 100 mg/dL (5.6 mmol/L), it is

in the range of 81-180 mg/dL (4.5-10.0 mmol/L). You may expect your CGM readings to be within 20% of YSI values 78% of the time.

Table 1-B. System Agreement to YSI within YSI Glucose Ranges

YSI Glucose Range mg/dL (mmol/L)	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent within 40/40% YSI	Percent Greater than 40/40% YSI
Overall	9152	71%	82%	92%	97%	3%
< 40 (2.2)	22	59%	73%	86%	100%	0%
40-60 (2.2-3.3)	461	75%	87%	94%	98%	2%
61-80 (3.4-4.4)	890	69%	81%	94%	98%	2%
81-180 (4.5-10.0)	3892	65%	76%	88%	95%	5%
181-300 (10.1-16.7)	2644	74%	85%	94%	97%	3%
301-350 (16.7-19.4)	869	79%	92%	99%	100%	0%
351-400 (19.4-22.2)	337	84%	91%	98%	100%	0%
> 400 (22.2)	37	81%	86%	100%	100%	0%

NOTE: CGM readings are within 40-400 mg/dL (2.2-22.2 mmol/L), inclusive.

Table 1-B is categorized within YSI reference value ranges. When you know your blood glucose level (measured by YSI in the study), this table shows how likely your CGM reading matches with your blood glucose

level. For example if you feel normal and your blood glucose level is at 100 mg/dL (5.6 mmol/L), you can expect your CGM reading to be within 20% of YSI values, i.e. 80 to 120 mg/dL (4.5-6.7 mmol/L), 76% of the time.

During the clinical study, the reference YSI values outside of the System measurable range were collected. Among these samples, on 22 occasions, when the actual blood glucose concentrations (as determined by the YSI analyzer) were lower than 40 mg/dL (2.2 mmol/L), 73% of the paired CGM glucose readings were within 20 mg/dL (1.1 mmol/L) of the YSI values, and 86% of the paired CGM glucose readings were within 30 mg/dL (1.7 mmol/L) of the YSI values. On 37 occasions, when the actual blood glucose concentration (as determined by the YSI analyzer) were greater than 400 mg/dL (22.2 mmol/L), 86% of paired System readings were within 20% of the YSI values, and 100% of the paired CGM glucose readings were within 30% of the YSI values.

Agreement When CGM Reads "LOW" or "HIGH"

The System reports glucose concentrations between 40 and 400 mg/dL (2.2-22.2 mmol/L). When the System determines the glucose level is below 40 mg/dL (2.2 mmol/L), it displays "LOW" in the Receiver Status Box. When the Dexcom G4 PLATINUM System determines that the glucose level is above 400 mg/dL (22.2 mmol/L), it displays "HIGH" in the Receiver Status Box. Because the System does not display glucose values below 40 mg/dL (2.2 mmol/L) or above 400 mg/dL (22.2 mmol/L), the comparisons to the actual blood glucose concentrations (as determined by the YSI analyzer) when CGM is classified as "LOW" or "HIGH" are included separately in Table 2. The table includes the numbers and the cumulative percentages when YSI values were less than certain glucose levels (for 'LOW'), and when YSI values were greater than certain glucose levels (for 'HIGH').

For example, on 155 occasions, the System displayed "LOW", 92% (141 out of 155) of YSI values were less than 80 mg/dL (4.4 mmol/L), and only 79% (123 out of 155) of the YSI values were less than 70 mg/dL (3.9 mmol/L); On 248 occasions, the System displayed "HIGH", 99% (246 out of 248) of the YSI values were greater than 240 mg/dL (13.3

mmol/L), and 96% (238 out of 248) of the YSI values were greater than 280 mg/dL (15.6 mmol/L).

Table 2. Number and Percentage of YSI Values When CGM Readings are 'Low' or 'High'

		YSI mg/dL (mmol/L)					Total
CGM Readings	CGM-YSI pairs	< 55 (3.1)	< 60 (3.3)	< 70 (3.9)	< 80 (4.4)	> 80 (4.4)	
'LOW'	n	66	18	39	19	13	155
	Cumulative Percent	42%	54%	79%	92%	8%	
		YSI mg/dL (mmol/L)					Total
CGM Readings	CGM-YSI pairs	> 340 (18.9)	> 320 (17.8)	> 280 (15.6)	> 240 (13.3)	< 240 (13.3)	
'HIGH'	n	189	31	18	8	2	248
	Cumulative Percent	76%	89%	96%	99%	1%	

Concurrence of System and Laboratory Reference

The percentage of concurring CGM readings and YSI reference values were included in Table 3. For example, when CGM readings are within 81 to 120 mg/dL (4.4-6.7 mmol/L), you can expect your blood glucose levels are within 40 to 60 mg/dL (2.2-3.3 mmol/L) 2% of time; within 60 to 80 mg/dL (3.3-4.4 mmol/L) 17% of time; within 81 to 120 mg/dL (4.4- 6.7 mmol/L) 66% of time; within 121 to 160 mg/dL (6.7 to 8.9 mmol/L) 13% of time; and within 161 to 180 mg/dL (8.9 to 10 mmol/L) 1% of time.

Table 3 is categorized by each range of CGM glucose ranges. This table describes for each range of CGM glucose readings, what percentage of paired YSI values were in the same glucose range (shaded) or in

glucose ranges above and below the paired CGM readings.

Table 3. Concurrence of CGM Readings and YSI Values

CGM mg/dL (mmol/L)	YSI mg/dL (mmol/L) Percent of matched pairs in each YSI glucose range for each Sensor glucose range											
	< 40 (<2.2)	40-60 (2.2-3.3)	61-80 (3.4-4.4)	81-120 (4.5-6.7)	121-160 (6.7-8.9)	161-200 (8.9-11.1)	201-250 (11.1-13.9)	251-300 (13.9-16.7)	301-350 (16.7-19.4)	351-400 (19.4-22.2)	> 400 (> 22.2)	Number of Paired CGM-YSI
< 40 (< 2.2)	6%	48%	37%	7%	1%	0%	0%	0%	0%	0%	0%	155
40-60 (2.2-3.3)	4%	49%	36%	11%	1%	0%	0%	0%	0%	0%	0%	512
61-80 (3.4-4.4)	0%	22%	51%	24%	1%	0%	0%	0%	0%	0%	0%	781
81-120 (4.5-6.7)	0%	2%	17%	66%	13%	1%	0%	0%	0%	0%	0%	1706
121-160 (6.7-8.9)	0%	0%	1%	25%	60%	13%	2%	0%	0%	0%	0%	1492
161-200 (8.9-11.1)	0%	0%	0%	2%	28%	53%	16%	2%	0%	0%	0%	1240
201- 250 (11.1- 13.9)	0%	0%	0%	0%	3%	21%	51%	21%	3%	1%	0%	1181
251- 300 (13.9- 16.7)	0%	0%	0%	0%	0%	4%	19%	49%	24%	3%	0%	1018
301- 350 (16.7- 19.4)	0%	0%	0%	0%	0%	0%	3%	28%	51%	16%	1%	775
351- 400 (19.4- 22.2)	0%	0%	0%	0%	0%	0%	3%	10%	43%	38%	7%	447
> 400 (> 22.2)	0%	0%	0%	0%	0%	0%	1%	6%	21%	57%	15%	248

Accuracy

Accuracy between matched pairs was also estimated by calculating the percent difference between the System reading and the YSI value. For example, if the YSI value is 100 mg/dL (5.6 mmol/L) and the System

reading is 90 mg/dL (5.0 mmol/L), a 10% difference between the System and the YSI is reported. The System and YSI values were compared by pairing the System reading that fell immediately after the YSI value was collected.

In the example above the System reading is less than the YSI value, so the percent difference reading is negative. The mean percent difference is the average of all positive and negative percent differences between the two devices; it tells you if the System reads higher or lower on average than the YSI at each glucose range.

Another estimate used to show the accuracy of the System is the absolute percent difference. The absolute percent difference tells you the percent difference or “distance” between the System and YSI values, but does not tell you whether the System is reading, on average, higher or lower than the YSI laboratory standard. The mean absolute percent difference is the average “distance” (regardless if positive or negative) between System readings and YSI values.

These accuracy measures in differences are based on 9152 paired glucose results and summarized in the following Table 4-A and Table 4-B.

Overall, the System reads, on average, 2.9% different (Mean Percent Difference) than the reference and 13.3% absolute different (Mean Absolute Difference) than the reference values. The Median Percent Difference shows that half of the time the System reads 1.7% or less than the YSI blood glucose values and the Median Absolute Percent Difference shows that half of the time the System reads about 9.8% or less different than YSI blood glucose values.

Table 4-A. System Difference to YSI within CGM Glucose Ranges

CGM Glucose Ranges mg/dL (mmol/L)	Number of Paired CGM-YSI	Mean Percent Difference (%)	Median Percent Difference (%)	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)
Overall	9152	2.9	1.7	13.3	9.8
*40-60 (2.2-3.3)	512	-10.0 (-0.6)	-8.2 (-5.2)	13.5 (0.8)	9.7 (0.5)
*61-80 (3.4-4.4)	781	-2.4 (-0.1)	-0.4 (-0.0)	11.4 (0.6)	8.6 (0.5)
81-180 (4.5-10.0)	3853	4.8	3.0	13.8	9.8
181-300 (10.1-16.7)	2784	2.1	0.0	11.9	9.2
301-350 (16.7-19.4)	775	3.8	2.8	9.8	7.9
351-400 (19.4-22.2)	447	10.4	7.7	12.8	9.1

* For CGM ≤ 80 mg/dL (4.4 mmol/L), the differences in mg/dL (mmol/L) are included instead of percent differences (%).

NOTE: CGM readings are within 40 to 400 mg/dL (2.2- 22.2 mmol/L), inclusive.

Table 4-A is categorized within CGM glucose ranges. For example, on average, CGM reads 10.0 mg/dL (0.6 mmol/L) lower than the reference at CGM glucose levels of 40-60 mg/dL (2.2-3.3 mmol/L) and reads 2.4 mg/dL (0.1 mmol/L) lower than the reference at CGM glucose level of 61-80 mg/dL (Mean Difference, i.e. 3.4-4.4 mmol/L), 9.8% different than the reference at CGM glucose values of 301-350 mg/dL (Mean Absolute Percent Difference, i.e. 16.7-19.4 mmol/L), and 12.8% different than

the reference at CGM reading within 351-400 mg/dL (Mean Absolute Percent Difference, i.e. 19.4-22.2 mmol/L).

Table 4-B. System Difference to YSI within YSI Glucose Ranges

YSI Glucose Ranges mg/dL (mmol/L)	Number of paired CGM-YSI	Mean Percent Difference (%)	Median Percent Difference (%)	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)
Overall	9152	2.9	1.7	13.3	9.8
*< 40 (2.2)	22	14.4 (0.8)	12.9 (0.7)	14.4 (0.8)	12.9 (0.7)
*40-60 (2.2-3.3)	461	7.3 (0.4)	6.3 (0.4)	11.0 (0.4)	8.8 (0.5)
*61-80 (3.4-4.4)	890	3.6 (0.2)	2.4 (0.1)	12.2 (0.7)	10.2 (0.6)
81-180 (4.5-10.0)	3892	3.8	3.0	14.0	10.1
181-300 (10.1-16.7)	2644	1.3	0.3	11.2	8.5
301-350 (16.7-19.4)	869	-1.7	-1.5	9.8	8.6
351-400 (19.4-22.2)	337	-5.8	-5.2	8.8	6.8
> 400 (22.2)	37	-11	-10	11.2	10.3

* For YSI ≤ 80 mg/dL (4.4 mmol/L), the differences in mg/dL (mmol/L) are included instead of percent differences (%).

NOTE: CGM readings are within 40 to 400 mg/dL (2.2-22.2 mmol/L), inclusive.

Table 4-B is categorized within YSI glucose value ranges. For example,

on average, CGM reads 7.3 mg/dL (0.4 mmol/L) higher than the reference at YSI glucose levels of 40-60 mg/dL (2.2-3.3 mmol/L) and reads 3.6 mg/dL (0.2 mmol/L) higher than the reference at YSI glucose level of 61-80 mg/dL (Mean Difference, i.e. 3.4-4.4 mmol/L), 9.8% different than the reference at YSI glucose values of 301-350 mg/dL (Mean Absolute Percent Difference, i.e. 16.7-19.4 mmol/L), and 8.8% different than the reference at YSI glucose values of 351-400 mg/dL (Mean Absolute Percent Difference, i.e. 19.4-22.2 mmol/L).

Low and High Glucose Alerts

The ability of the System to detect high and low glucose levels (concentrations) is assessed by comparing System results to YSI results at low and high blood glucose levels and determining if the alert may have sounded. The System and YSI readings were compared by pairing the System reading that occurred immediately after the YSI reading was collected. There were 9555 paired System and YSI results evaluated. We suggest that you ask your doctor what alert settings would be best for you.

The Low Glucose Alert

Estimates of how well the adjustable Low Glucose Alert performs are presented in Table 5.

Table 5. Hypoglycemic Alert Evaluation

Hypoglycemic Alert Level mg/dL (mmol/L)	True Alert Rate	False Alert Rate	Hypoglycemia Detection Rate	Hypoglycemia Missed Detection Rate
55 (3.1)	50%	50%	71%	29%
60 (3.3)	64%	36%	75%	25%
70 (3.9)	79%	21%	83%	17%
80 (4.4)	87%	13%	86%	14%
90 (5.0)	90%	10%	89%	11%

Hypoglycemia Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the % of time the device alarmed when the blood glucose level was at or below the alert setting within 15 minutes before or after the device alarmed. The False Alert Rate is the % of time the device alarmed when the blood glucose level was above the alert setting within 15 minutes before or after the device alarmed.

For example, if you set the Low Glucose Alert to 70 mg/dL (3.9 mmol/L) and your alarm sounds, how often can you expect your blood sugar to actually be low? If your alarm sounds, you can expect your blood sugar to be below 70 mg/dL (3.9 mmol/L) approximately 79% of the time and not be below 70 mg/dL (3.9 mmol/L) approximately 21% of the time within the 15 minute period before or after your alarm sounds.

Hypoglycemia Detection Rate

The Detection Rate shows how often the device recognizes and alerts you to an episode of hypoglycemia or how often it misses such an event. The Hypoglycemia Detection Rate is the % of time the blood glucose level was at or below the alert setting and device alarmed within 15 minutes before or after the blood glucose was at or below the alert settings. The Hypoglycemia Missed Detection Rate is the % of time the blood glucose was at or below the alert setting, but the device did not alarm within 15 minutes before or after the blood glucose was at or below the alert setting.

For example, if you set the Low Glucose alert to 70 mg/dL (3.9 mmol/L), how often will your alarm alert you if your blood glucose goes below 70 mg/dL (3.9 mmol/L)? If your blood sugar goes below 70 mg/dL (3.9 mmol/L), you can expect your alarm to sound 83% of the time and not to sound approximately 17% of time within the 15 minute period before or after your blood sugar goes below 70 mg/dL(3.9 mmol/L).

The High Glucose Alert

Estimates of how well the adjustable High Glucose Alert performs are presented in Table 6.

Table 6. Hyperglycemic Alert Evaluation

Hyperglycemic Alert Level mg/dL (mmol/L)	True Alert Rate	False Alert Rate	Hyperglycemia Detection Rate	Hyperglycemia Missed Detection Rate
120 (6.7)	95%	5%	98%	2%
140 (7.8)	94%	6%	97%	3%
180 (10.0)	92%	8%	97%	3%
200 (11.1)	92%	8%	97%	3%
220 (12.2)	91%	9%	95%	5%
240 (13.3)	91%	9%	94%	6%
300 (16.7)	82%	18%	86%	14%

Hyperglycemia Alert Rate

The Alert Rate shows how often the alert is right or wrong. The True Alert Rate is the % of time the device alarmed when the blood glucose level was at or above the alert setting within 15 minutes before or after the device alarmed. The False Alert Rate is the % of time the device alarmed when the blood glucose level was below the alert setting within 15 minutes before or after the device alarmed.

For example, if you set the High Glucose alert to 200 mg/dL (11.1 mmol/L) and your alarm sounds, how often can you expect your blood sugar to actually be high? If your alarm sounds, you can expect your blood sugar to be at or above 200 mg/dL (11.1 mmol/L) approximately 92% of the time and not be above 200 mg/dL (11.1 mmol/L) approximately 8% of the time within the 15 minute period before or after your alarm sounds.

Hyperglycemia Detection Rate

The Detection Rate shows how often the device recognizes and alerts you to an episode of hyperglycemia or how often it misses such an

event. The Hyperglycemia Detection Rate is the % of time the blood glucose level was at or above the alert setting and the device alarmed within 15 minutes before or after the blood glucose was at or above the alert settings. The Hyperglycemia Missed Detection Rate is the % of time the blood glucose was at or above the alert setting, but the device did not alarm within 15 minutes before or after the blood glucose was at or above the alert setting.

For example, if you set your High Glucose alert to 200 mg/dL (11.1 mmol/L), how often will your alarm alert you if your blood glucose goes at or above 200 mg/dL (11.1 mmol/L)? If your blood sugar goes above 200 mg/dL (11.1 mmol/L), you can expect your alarm to sound 97% of the time and not to sound approximately 3% of time within the 15 minute period before or after your blood sugar goes above 200 mg/dL (11.1 mmol/L).

Calibration Stability

The System must be calibrated every 12 hours. To demonstrate performance of the System over a 12-hour calibration period, sensors were evaluated to verify that performance remains consistent over the 12-hour calibration period. Systems were evaluated in 2-hour increments after calibration. Performance was estimated at each 2-hour interval and stratified by glucose concentrations by calculating the percentage of System readings within 15 mg/dL (0.9 mmol/L) or 15%, 20 mg/dL (1.1 mmol/L) or 20%, 30 mg/dL (1.7 mmol/L) or 30%, 40 mg/dL (2.2 mmol/L) or 40% and greater than 40 mg/dL (2.2 mmol/L) or 40% of the YSI values in Table 7.

Table 7. Percentage of System Readings within YSI Values with Data Stratified in 2-Hour Increments after Calibration

Time from Calibration	Number of paired CGM-YSI	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent within 40/40% YSI	Percent greater than 40/40% YSI
0-2 hours	1929	78%	88%	96%	98%	2%
2-4 hours	1516	69%	81%	91%	96%	4%
4-6 hours	1547	69%	79%	91%	95%	5%
6-8 hours	1520	68%	79%	92%	97%	3%
8-10 hours	1555	71%	82%	92%	96%	4%
10-12 hours	1068	65%	77%	91%	96%	4%
12-14 hours	17	65%	76%	82%	88%	12%

NOTE: CGM readings are within 40 to 400 mg/dL (2.2-22.2 mmol/L), inclusive.

Sensor Stability

Sensors can be worn for up to 7 days. To verify sensor performance over time, 108 sensors were evaluated across the 7-day wear period. Performance was estimated by calculating the percentage of System readings within 15 mg/dL (0.9 mmol/L) or 15%, 20 mg/dL (1.1 mmol/L) or 20%, 30 mg/dL (1.7 mmol/L) or 30% , 40 mg/dL (2.2 mmol/L) or 40% and greater than 40 mg/dL (2.2 mmol/L) or 40% of the YSI values at the beginning (Day 1), middle (Day 4) and end (Day 7) of the System lifecycle. The average and median of the absolute percent differences are included in Table 8 showing consistent accuracy and sensor stability over the 7-day life of the sensor.

Table 8. Sensor Stability (Accuracy over Time)

Day of Wear	Number of paired CGM-YSI	Mean Absolute Percent Differences (%)	Median Absolute Percent Differences (%)	Percent within 15/15% YSI	Percent within 20/20% YSI	Percent within 30/30% YSI	Percent within 40/40% YSI	Percent greater than 40/40% YSI
Day 1	3023	16.7%	13.2%	59%	71%	86%	94%	6%
Day 4	3108	11.4%	8.2%	77%	87%	95%	98%	2%
Day 7	3021	11.9%	8.9%	76%	87%	95%	98%	2%

NOTE: CGM readings are within 40 to 400 mg/dL (2.2-22.2 mmol/L), inclusive.

Precision of System Readings

In the study, 36 participants wore two Systems. This was to look at how similarly two Systems function on the same patient (sensor precision). Precision was evaluated by comparing the glucose readings from the two Systems worn on the same subject at the same time. Results showed that System readings from the two sensors generally agreed with each other within 9% (absolute percent difference) with a 7% coefficient of variation.

Sensor Life

Sensors may be worn for up to 7 days (168 hours). To estimate how long a sensor will work over 7 days, 108 sensors were evaluated to determine how many days/hours of readings each sensor provided. Ninety-four percent (94%) of the sensors lasted until Day 7 (145-168 hours). There were 6 (4%) sensors that ended early, four of which lasted more than 3 days.

Number of Readings Provided

The System is capable of providing a reading up to every 5 minutes, or up to 288 readings per day. For a variety of reasons, the System may not display a glucose reading and readings are “skipped.” Table 9 estimates the number of readings you can expect to receive from

the System over the entire 7-day period after calibration. For example, 93.5% of Systems provided between 1,811 and 1,992 valid glucose readings (or more than 76% of the expected number of readings). Adjusted within each system wear-day, the System provided an average of 97% of all expected glucose readings (288) as seen in Table 10.

Table 9. Number of Readings Provided by Each Sensor Over 7-Days

% of Total Possible Readings Provided	Total Readings Provided (Min-Max)	% of Systems Providing that Number of Readings
0-25%	167-491	1.9%
26-50%	719-914	3.7%
51-75%	1267-1267	0.9%
76-100%	1811-1992	93.5%

Table 10. System Readings Within Wear Days

Statistic	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	All Days (N = 108)
Mean	98%	98%	98%	98%	97%	99%	95%	97%
Median	100%	100%	100%	100%	100%	100%	100%	100%
STD	5%	3%	9%	8%	10%	3%	11%	8%

Agreement and Accuracy Relative to SMBG

During the study, agreement between the System and blood glucose values is also characterized using paired System and SMBG results. The System and SMBG values were compared by pairing the comparative SMBG value to a System glucose reading that occurred immediately after the SMBG was collected. These results characterize the performance patients expect during real-time use of the system in

their daily diabetes management when comparing the system readings to their home blood glucose meter results.

Table 11. System Agreement to SMBG Within CGM Glucose Ranges

CGM Glucose Ranges mg/dL (mmol/L)	Number of paired CGM-SMBG	Percent within 15/15% SMBG	Percent within 20/20% SMBG	Percent within 30/30% SMBG	Percent within 40/40% SMBG	Percent greater than 40/40% SMBG
Overall	7508	69%	81%	94%	98%	2%
40-60 (2.2-3.3)	731	75%	84%	92%	96%	4%
61-80 (3.4-4.4)	968	78%	86%	95%	99%	1%
81-180 (4.5-10.0)	3141	65%	78%	93%	98%	2%
181-300 (10.1-16.7)	1960	68%	81%	94%	97%	3%
301-350 (16.7-19.4)	450	77%	88%	98%	99%	1%
351-400 (19.4-22.2)	258	75%	85%	95%	98%	2%

NOTE: CGM readings are within 40 to 400 mg/dL (2.2-22.2 mmol/L), inclusive.

Table 11 is categorized within CGM glucose ranges. For readings less than or equal to 80 mg/dL (4.4 mmol/L) the absolute difference in mg/dL (mmol/L) between the two glucose results was calculated. For values greater than 80 mg/dL (4.4 mmol/L) the absolute percent difference (%) from the SMBG values was calculated. The percentages of total readings within 15 mg/dL (0.8 mmol/L) or 15%, 20 mg/dL (1.1 mmol/L) or 20%, 30 mg/dL (1.7 mmol/L) or 30%, 40 mg/dL (2.2 mmol/L) or 40%

or greater than 40 mg/dL (2.2 mmol/L) or 40% were then calculated. For example, if the CGM reads 100 mg/dL, it is between 81-180 mg/dL (4.5-10.0 mmol/L) range, you can expect the CGM readings to be within 20% of the SMBG values 78% time.

Table 12. System Difference to SMBG within CGM Glucose Ranges

CGM Glucose Ranges mg/dL (mmol/L)	Number of Paired CGM-SMBG	Mean Percent Difference (%)	Median Percent Difference (%)	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)
Overall	7508	-0.4	-1.4	14.0	11.0
*40-60 (2.2-3.3)	731	-9.3 (-0.5)	-8.0 (-0.4)	11.7 (0.7)	8.0 (0.4)
*61-80 (3.4-4.4)	968	-1.0 (-0.1)	1.0 (0.1)	10.7 (0.6)	8.0 (0.4)
81-180 (4.5-10.0)	3141	1.4	0.0	14.2	11.0
181-300 (10.1-16.7)	1960	-0.7	-2.8	13.0	10.3
301-350 (16.7-19.4)	450	-0.7	-2.6	10.5	8.6
351-400 (19.4-22.2)	258	5.0	3.0	11.9	8.6

* For CGM ≤ 80 mg/dL (4.4 mmol/L), the differences in mg/dL (mmol/L) are included instead of percent differences (%).

NOTE: CGM readings are within 40 to 400 mg/dL (2.2-22.2 mmol/L), inclusive.

Overall, the System reads, on average, 0.4% lower (Mean Percent Difference) than SMBG values and 14.0% absolute different (Mean Absolute Percent Difference) than the SMBG values. The Median

Percent Difference shows that half of the time the System reads -1.4% or less than the SMBG values and the Median Absolute Percent Difference shows that half of the time the System reads about 11.0% or less different than SMBG values (Table 12).

Adverse Events

No serious adverse events or device-related serious adverse events occurred during the study. Mild skin irritation, such as erythema or edema, occurred in low frequency around adhesive area. No infection, bruising, or bleeding occurred at the sensor needle insertion area or the adhesive area.

14.2 PRODUCT SPECIFICATIONS

Sensor Product Specifications

Glucose Range	40 - 400 mg/dL
Sensor Life	Up to 7 days
Calibration	Commercially available blood glucose meter
Calibration Range	40 - 400 mg/dL
Storage Condition	Temperature: 36° F - 77° F Humidity: 15% - 85% RH
Sterilization	Sterile by radiation

Transmitter Product Specifications

Part Number	9438-01
Dimensions (including sensor pod)	Length: 1.5 inches Width: 0.9 inches Thickness: 0.5 inches
Weight (including sensor pod)	0.4 ounces

(continued on next page)

Transmitter Product Specifications (continued from page before)

Power Supply	Silver oxide batteries (not replaceable)
Operational Conditions	Temperature: 50° F - 108° F Humidity: 10% - 95% RH
Storage Conditions	Temperature: 32° F - 113° F Humidity: 10% - 95% RH
Operating Altitude	-500 to 12000 feet
Limited Warranty	6 months
Moisture Protection	IP28: temporary submersion
Protection Against Electrical Shock	Type BF applied part

Transmitter Performance Characteristics

Parameter	Performance Characteristic
TX/RX Frequencies	2.424 999 877 GHz 2.449 993 677 GHz 2.474 737 539 GHz 2.477 236 919 GHz
Bandwidth	334.7 kHz
Maximum Output Power	1.25 mW EIRP
Modulation	Minimum Shift Key
Data Rate	49.987 Kbits/Sec
Total Packet	224 bits
Transmit Duty Cycle	4.48 ms every 5 minutes at each of the four TX frequencies.
Data Detection Range	20 feet

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The Dexcom G4 PLATINUM Professional Continuous Glucose Monitoring System is safe for use on U.S. commercial airlines. The Dexcom G4 PLATINUM Transmitter is an M-PED with emission levels that meet RTCA/DO160, Section 21, Category M. Per FAA Advisory, Circular #91-21, 1B, dated 8/25/06, any M-PED that meets this standard in all modes may be used onboard the aircraft without any further testing by the operator. This device can withstand exposure to common electrostatic (ESD) and electromagnetic interference (EMI).

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The transmitter (P/N 9438-01) is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the transmitter should ensure that it is used in such an environment.

Transmitter Electromagnetic Immunity Specifications

Immunity Test	IEC 60601 Test Level	Transmitter Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) **IEC 61000-4-2**	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient /burst	± 2 kV for power supply lines	Not applicable	

(continued on next page)

Transmitter Electromagnetic Immunity Specifications
(continued from page before)

Immunity Test	IEC 60601 Test Level	Transmitter Compliance Level	Electromagnetic Environment Guidance
IEC 61000-4-4	± 1 kV for input/output lines	Battery operated	
Surge **IEC 61000-4-5**	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable Battery operated	
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines **IEC 61000-4-11**	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Not applicable Battery operated	

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Transmitter Electromagnetic Immunity Specifications
(continued from page before)

Immunity Test	IEC 60601 Test Level	Transmitter Compliance Level	Electromagnetic Environment Guidance
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: *U_T is the a.c. mains voltage prior to application of the test level.*

Receiver Product Specifications

Part Number	MT20649
Reading Frequency	Every 5 minutes
Dimensions	Length: 4.0 inches Width: 1.8 inches Thickness: 0.5 inches
Weight	2.4 ounces
Receiver Input	5V DC, 1A
Power Supply	MT21255
Communication Range	20 feet
Memory Storage	30 days of glucose data, 7 days of tech support data
Re-Chargeable Battery Use	3 days

(continued on next page)

Receiver Product Specifications (continued from page before)

Charging Time	3 hours wall outlet, 5 hours powered USB
Storage/Operating Conditions	Temperature: 32° F - 113° F Humidity: 10% - 95% RH
Operating Altitude	-500 to 12000 feet
Moisture Protection	IP22: vertically falling drops
Limited Warranty	1 year
Control Classification	Class II equipment

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The receiver (P/N MT20649) is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the receiver should ensure that it is used in such an environment.

Receiver Electromagnetic Immunity Specifications

Immunity Test	IEC 60601 Test Level	Receiver Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) **IEC 61000-4-2**	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

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Receiver Electromagnetic Immunity Specifications
(continued from page before)

Immunity Test	IEC 60601 Test Level	Receiver Compliance Level	Electromagnetic Environment Guidance
Electrical Fast Transient /burst **IEC 61000-4-4**	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge **IEC 61000-4-5**	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles	Mains power quality should be that of a typical commercial or hospital environment.

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Receiver Electromagnetic Immunity Specifications
(continued from page before)

Immunity Test	IEC 60601 Test Level	Receiver Compliance Level	Electromagnetic Environment Guidance
IEC 61000-4-11 **IEC 60601-1-11**	70% U_T (30% dip in U_T) for 25 cycles 85% U_T (15% dip in U_T) for 5 sec < 5% U_T (> 95% dip in U_T) for 5 sec	70% U_T (30% dip in U_T) for 25 cycles 85% U_T (15% dip in U_T) for 5 sec < 5% U_T (> 95% dip in U_T) for 5 sec	
Power Frequency (50/60 Hz) Magnetic Field **IEC 61000-4-8**	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: *U_T is the a.c. mains voltage prior to application of the test level.*

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Dexcom G4 PLATINUM Professional System is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the Dexcom G4 PLATINUM Professional System should ensure that it is used in such an environment.

System Electromagnetic Immunity Specifications

Immunity Test	IEC 60601 Test Level	Receiver Compliance Level	Electromagnetic Environment Guidance
Conducted RF **IEC 61000- 4-6** **(Receiver only)** **Radiated RF** **IEC 61000-4-3**	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the receiver, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance** d = 1.2 √P 150 kHz to 80 MHz d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz

(continued on next page)

System Electromagnetic Immunity Specifications
(continued from page before)

Immunity Test	IEC 60601 Test Level	Receiver Compliance Level	Electromagnetic Environment Guidance
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with following symbol:

NOTE 1: *At 80 MHz and 800 MHz, the higher frequency range applies.*

NOTE 2: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Dexcom G4 PLATINUM Professional System is used exceeds the applicable RF compliance level above, the Dexcom G4 PLATINUM Professional System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Dexcom G4 PLATINUM Professional System.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Dexcom G4 PLATINUM Professional System is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the Dexcom G4 PLATINUM Professional System should ensure that it is used in such an environment.

Electromagnetic Emissions Specifications

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions **CISPR 11**	Group 1	The Dexcom G4 PLATINUM Professional System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

(continued on next page)

Electromagnetic Emissions Specifications (continued from page before)

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions **CISPR 11**	Class B	The Dexcom G4 PLATINUM Professional System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions **IEC 61000-3-2**	Not applicable	
Voltage fluctuations/flicker emissions **IEC 61000-3-3**	Not applicable	

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Receiver

The receiver is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the receiver can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the receiver as recommended below, according to the maximum output power of the communications equipment. Portable and mobile RF equipment include: baby monitors, Bluetooth wireless headsets, wireless routers, microwave ovens, laptops with internal wi-fi adapters, GSM cell phones, RFID scanners and hand-held security metal detector often used by security screeners.

Minimum Recommended Distance Between Transmitter and Receiver

Rated maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\ P^{1/2}$	80 MHz to 800 MHz $d = 1.2\ P^{1/2}$	800 MHz to 2.5 GHz $d = 2.3\ P^{1/2}$
0.01 0.1 1 10 100	0.12 0.38 1.2 3.8 12	0.12 0.38 1.2 3.8 12	0.23 0.73 2.3 7.3 23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in feet can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture.

NOTE 1: *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*

NOTE 2*: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

USB Charging/Download Cable* Specifications

Dexcom P/N	MT20655
Input/Output	5V DC, 1A
Type	USB A to USB micro B
Length	3 feet

* The power supply/charger can be connected to the USB charging/download cable for charging using an AC power outlet.

Power Supply/Charger Specifications

Dexcom P/N	MT21255
Class	II
Input:	AC Input 100-240 Vac, 50/60Hz, 0.2A, 0.2A rms at 100Vac
DC Output:	5V DC, 1A (5.0 Watts)

14.3 FCC REQUIREMENTS

The transmitter covered by this user's guide has been certified under FCC ID: PH29433.

Although the transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from the transmitter will be free from interference.

Compliance Statement (Part 15.19)

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:
1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Warning (Part 15.21)

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC Interference Statement (Part 15.105 (b))

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used

in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This portable transmitter with its antenna complies with FCC/IC RF exposure limits for general population/uncontrolled exposure.

chapter fifteen

USER ASSISTANCE

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CHAPTER 15: USER ASSISTANCE

Dexcom Website:
www.dexcom.com

Dexcom Address:
6340 Sequence Drive
San Diego, CA 92121

TECHNICAL SUPPORT

For Dexcom product questions and troubleshooting issues[8].

Dexcom Technical Support Phone Numbers:

1.877.339.2664 or 1.858.200.0200

(24 hours, 7 days a week)

Dexcom Technical Support E-mail:

TechSupport@dexcom.com

Dexcom Technical Support Fax:

1.877.633.9266

[8] Dexcom Technical Support does not offer medical advice.

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SALES SUPPORT

For help with first-time orders, re-orders, tracking shipments, and locating a Dexcom representative in your area. If, after using a Dexcom G4 PLATINUM Professional System, your patients would like to purchase a Dexcom CGM system for their personal use, please have them contact Dexcom Sales Support or their local Dexcom representative.

Dexcom Sales Support Phone Numbers:

1.877.339.2664 or 1.858.200.0200

Dexcom Sales Support E-mail:

CustomerService@dexcom.com

Dexcom Sales Support Fax:

1.877.633.9266

chapter sixteen

WARRANTY

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CHAPTER 16: WARRANTY

Dexcom G4 PLATINUM Professional System Limited Warranty

1. What is Covered and for How Long?

Dexcom, Inc. (“Dexcom”) provides a limited warranty to the original purchaser that the Dexcom G4 PLATINUM Receiver is free from defects in material and workmanship under normal use (“Limited Warranty”) for the period commencing upon the date of shipment and continuing for the following specified period of time after that date (“Warranty Period”):

Dexcom G4 PLATINUM Receiver: 1 Year

NOTE: If you received this receiver as a replacement for an in-warranty receiver, any remaining warranty on the original receiver shall transfer to this replacement receiver, and this warranty page shall be void.

2. What is Not Covered?

This Limited Warranty is conditioned upon proper use of the product by the purchaser. This Limited Warranty does not cover: (a) defects or damage resulting from accident, misuse, abuse, neglect, unusual physical, electrical or electromechanical stress, modification of any part of the product, or cosmetic damage; (b) equipment that has the ID number removed or made illegible; (c) all surfaces and other externally exposed parts that are scratched or damaged due to normal use; (d) malfunctions resulting from the use of the product in conjunction with accessories, products or ancillary or peripheral equipment not furnished or approved by Dexcom; (e) defects or damage from improper testing,

operation, maintenance, installation or adjustment; (f) installation, maintenance, and service of products; or (g) equipment that has been disassembled; or (h) water damage to the receiver (receiver is not water resistant, do not get the receiver wet at any time).

3. What are Dexcom's Obligations Under the Limited Warranty?

During the Warranty Period, Dexcom will replace, at Dexcom's sole option, without charge to purchaser, any defective Dexcom G4 PLATINUM Receiver. Purchaser must return the product to an authorized Dexcom Customer Support Department in an adequate container for shipping, accompanied by purchaser's sales receipt or comparable substitute proof of sale showing the date of purchase, the ID number of the product, and the seller's name and address. To obtain assistance on where to deliver the Dexcom G4 PLATINUM Receiver, call Dexcom Customer Support Department at **1.877.339.2664 or 1.858.200.0200**. Upon receipt, Dexcom will promptly replace the defective product. If Dexcom determines that any product is not covered by this Limited Warranty, purchaser must pay all shipping charges for the return of such product.

4. What are the Limits on Dexcom's Warranty and Liability Obligations?

THE LIMITED WARRANTY OF DEXCOM DESCRIBED ABOVE IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, STATUTORY OR OTHERWISE, AND DEXCOM EXPRESSLY EXCLUDES

AND DISCLAIMS ALL SUCH OTHER WARRANTIES, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT. EXCEPT TO THE EXTENT PROHIBITED BY APPLICABLE LAW, DEXCOM SHALL NOT BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, ARISING IN ANY WAY OUT OF THE SALE, USE, MISUSE OR INABILITY TO USE ANY DEXCOM G4 PLATINUM PROFESSIONAL SYSTEM. THIS LIMITATION SHALL APPLY EVEN IF DEXCOM OR ITS AGENT HAS BEEN ADVISED OF SUCH DAMAGES AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF THIS LIMITED REMEDY. THIS LIMITED WARRANTY SHALL NOT EXTEND TO ANYONE OTHER THAN THE ORIGINAL PURCHASER OF THIS PRODUCT AND STATES PURCHASER'S EXCLUSIVE REMEDY. IF ANY PORTION OF THIS LIMITED WARRANTY IS ILLEGAL OR UNENFORCEABLE BY REASON OF ANY LAW, SUCH PARTIAL ILLEGALITY OR ENFORCEABILITY SHALL NOT AFFECT THE ENFORCEABILITY OF THE REMAINDER OF THIS LIMITED WARRANTY WHICH PURCHASER ACKNOWLEDGES IS AND WILL ALWAYS BE CONSTRUED TO BE LIMITED BY ITS TERMS OR AS LIMITED AS THE LAW PERMITS.

Dexcom G4 PLATINUM Transmitter Limited Warranty

1. What Is Covered And For How Long?

Dexcom, Inc. ("Dexcom") provides a limited warranty to

the original purchaser that the Dexcom G4 PLATINUM Transmitter is free from defects in material and workmanship under normal use ("Limited Warranty") for the period commencing upon the date of shipment and continuing for the following specified period of time after that date ("Warranty Period"):

Dexcom G4 PLATINUM Transmitter: 6 Months

NOTE: If you received this transmitter as a replacement for an in-warranty transmitter, any remaining warranty on the original transmitter shall transfer to this replacement transmitter, and this warranty page shall be void.

2. What Is Not Covered?

This Limited Warranty is conditioned upon proper use of the product by the purchaser. This Limited Warranty does not cover: (a) defects or damage resulting from accident, misuse, abuse, neglect, unusual physical, electrical or electromechanical stress, modification of any part of the product, or cosmetic damage; (b) equipment that has the ID number removed or made illegible; (c) all surfaces and other externally exposed parts that are scratched or damaged due to normal use; (d) malfunctions resulting from the use of the product in conjunction with accessories, product or ancillary or peripheral equipment not furnished or approved by Dexcom; (e) defects or damage from improper testing, operation, maintenance, installation or adjustment; (f) installation, maintenance, and service of products; (g) equipment that has been disassembled, or (h) water damage to the transmitter beyond the specifications listed in the

Dexcom G4 PLATINUM Professional CGM System User's Guide, a copy of which was included with the Dexcom G4 PLATINUM Professional CGM System and may be found at www.dexcom.com.

3. What Are Dexcom's Obligations Under The Limited Warranty?

During the Warranty Period, Dexcom will replace, at Dexcom's sole option, without charge to purchaser, any defective Dexcom G4 PLATINUM Transmitter. Purchaser must return the product to an authorized Dexcom Customer Support Department in an adequate container for shipping, accompanied by purchaser's sales receipt or comparable substitute proof of sale showing the date of purchase, the ID number of the product, and the seller's name and address. To obtain assistance on where to deliver the Dexcom G4 PLATINUM Transmitter, contact Dexcom Customer Support Department at **1.877.339.2664 or 1.858.200.0200**. Upon receipt, Dexcom will promptly replace the defective product. If Dexcom determines that any product is not covered by this Limited Warranty, purchaser must pay all shipping charges for the return of such product.

4. What Are The Limits on Dexcom's Warranty And Liability Obligations?

THE LIMITED WARRANTY OF DEXCOM DESCRIBED ABOVE IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, STATUTORY OR OTHERWISE, AND DEXCOM EXPRESSLY EXCLUDES AND DISCLAIMS ALL SUCH OTHER WARRANTIES,

INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT. EXCEPT TO THE EXTENT PROHIBITED BY APPLICABLE LAW, DEXCOM SHALL NOT BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, ARISING IN ANY WAY OUT OF THE SALE, USE, MISUSE OR INABILITY TO USE ANY DEXCOM G4 PLATINUM PROFESSIONAL CGM SYSTEM. THIS LIMITATION SHALL APPLY EVEN IF DEXCOM OR ITS AGENT HAS BEEN ADVISED OF SUCH DAMAGES AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF THIS LIMITED REMEDY. THIS LIMITED WARRANTY SHALL NOT EXTEND TO ANYONE OTHER THAN THE ORIGINAL PURCHASER OF THIS PRODUCT AND STATE PURCHASER'S EXCLUSIVE REMEDY. IF ANY PORTION OF THIS LIMITED WARRANTY IS ILLEGAL OR UNENFORCEABLE BY REASON OF ANY LAW, SUCH PARTIAL ILLEGALITY OR ENFORCEABILITY SHALL NOT AFFECT THE ENFORCEABILITY OF THE REMAINDER OF THIS LIMITED WARRANTY WHICH PURCHASER ACKNOWLEDGES IS AND WILL ALWAYS BE CONSTRUED TO BE LIMITED BY ITS TERMS OR AS LIMITED AS THE LAW PERMITS.

Dexcom Receiver Shield

LIMITED WARRANTY – SEAL SHIELD LIMITED WARRANTY COVERS THE REPLACEMENT OF THE SHIELD ONLY. SEAL SHIELD CANNOT BE HELD RESPONSIBLE FOR DAMAGES TO THE DEXCOM G4

PLATINUM RECEIVER DUE TO MISUSE, AND IMPROPER INSTALLATION, CARE OR MAINTENANCE OF THE SHIELD. SEAL SHIELD'S LIMITED WARRANTY DOES NOT, UNDER ANY CIRCUMSTANCES, COVER THE DAMAGE, REPAIR, REPLACEMENT OR COST OF THE DEXCOM G4 PLATINUM RECEIVER OR DATA INSIDE.

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chapter seventeen

TRAVEL INFORMATION

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CHAPTER 17: TRAVEL INFORMATION

It is safe for you to go through the metal detector or be “handwanded” while wearing the Dexcom sensor and transmitter. If you’re concerned or uncomfortable about going through the walk-through metal detector, the Transportation Security Administration (TSA) states that you should notify the Security Office that you’re wearing a continuous glucose monitor and would like a full-body pat-down and a visual inspection of your Dexcom sensor and transmitter instead. Advise the Security Office that the sensor cannot be removed because it is inserted under the skin.

Instead of putting your Dexcom G4 PLATINUM Professional System through the x-ray, request that the TSA officer perform a visual inspection. This must be requested before the screening process begins. Your Dexcom G4 PLATINUM Professional System components that are not attached to your body (e.g., receiver, extra sensors) should be ready in a separate bag when you approach the Security Officer. For other medical supplies, such as medications, meters and strips, check the manufacturer’s instructions or the TSA website.

You may keep the receiver on before take-off, while in flight and after landing. The Dexcom G4 PLATINUM Professional Continuous Glucose Monitoring System is safe for use on U.S. commercial airlines. The Dexcom G4 PLATINUM Transmitter is an M-PED with emission levels that meet RTCA/DO160, Section 21, Category M. Per FAA Advisory, Circular #91-21, 1B, dated 8/25/06. Any M-PED that meets this standard in all modes may be used onboard the aircraft without any further testing by the operator. This device can withstand exposure to common electrostatic (ESD) and electromagnetic interference (EMI).

Visit the TSA’s website if you have any questions or concerns.

www.tsa.gov

E-mail: TSA-ContactCenter@dhs.gov

Phone: Call 1.866.289.9673

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chapter eighteen

APPENDIX

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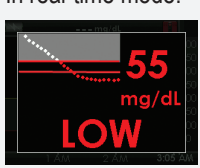
CHAPTER 18: APPENDIX
APPENDIX I, RECEIVER ALERTS, ALARM AND PROMPTS

The following tables describe the alarm, alerts and prompts and how the receiver notifies you in both real-time and blinded modes.

Prompt - Shows on screen only. Silent, no vibrate or beep.
Alert - Notifies with vibrate and beep depending on the profile settings.
Alarm - Low 55 - Notifies with vibrate and beep. Cannot be changed. Disabled in blinded mode.

Receiver Alerts, Alarm and Prompts

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
In real-time mode: 	Low glucose alarm	The most recent sensor glucose reading is at or below 55 mg/dL.	Vibrates 4 times and then vibrates/beeps 4 times every 5 minutes until confirmed or the glucose value goes above 55 mg/dL.	Yes, every 30 minutes after each confirmation until the blood glucose value comes back into range.
In blinded mode: No display	Disabled	N/A	Disabled	Disabled

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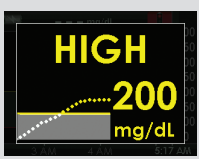
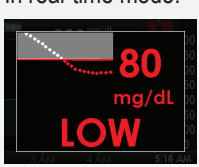
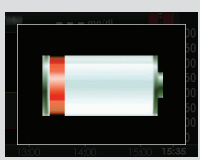
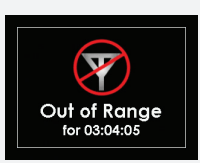
Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
In real-time mode: 	High glucose alert	The most recent sensor glucose reading is at or above the high alert setting.	Vibrates 2 times and then vibrates/beeps 2 times every 5 minutes until confirmed or the glucose value drops below the alert level.	No, unless you have turned on the high snooze feature. See Chapter 9, Section 9.2, Advanced Alerts.
In blinded mode: No display	Disabled	N/A	Disabled	Disabled
In real-time mode: 	Low glucose alert	The most recent sensor glucose reading is at or below the low alert setting.	Vibrates 3 times and then vibrates/beeps 3 times every 5 minutes until confirmed or the glucose value goes above the alert level.	No, unless you have turned on the low snooze feature. See Chapter 9, Section 9.2, Advanced Alerts.
In blinded mode: No display	Disabled	N/A	Disabled	Disabled

(continued on next page)

Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
In both real-time and blinded modes: 	Low battery alert	The receiver battery is low. Charge the receiver as soon as possible when you see this alert.	Vibrates 1 time at 20% battery capacity left.	Yes, at 10% battery capacity left.
In both real-time and blinded modes: 	Out of Range alert	The transmitter and receiver are not communicating and you will not receive sensor glucose readings.	Vibrates 1 time and then vibrates/beeps every 5 minutes until the receiver and transmitter are back in range.	No, unless you have turned on the out of range alert under the Alerts, Advanced menu option.

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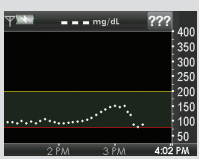
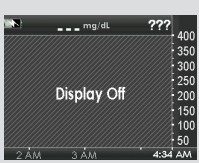
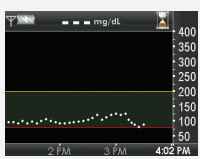
Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
In real-time mode: 	Glucose reading error prompt	The sensor is sending sensor glucose readings that the receiver does not understand. You will not receive sensor glucose readings.	Symbol in status area only.	N/A
In blinded mode: 	Glucose reading error prompt	The sensor is sending sensor glucose readings that the receiver does not understand. You will not be recording sensor glucose readings.	Symbol in status area only.	N/A

(continued on next page)

Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
In real-time mode: 	Wait prompt	The receiver has detected a potential problem with the sensor signal. You should wait about 30 minutes for more prompts. Do not enter any blood glucose values during this time. You will not receive sensor glucose readings.	Symbol in status area only.	N/A
In blinded mode:	Wait prompt	The receiver has detected a potential problem with the sensor signal. You should wait about 30 minutes for more prompts. Do not enter any blood glucose values during this time. You will not receive or record sensor glucose readings.	Symbol in status area only.	N/A

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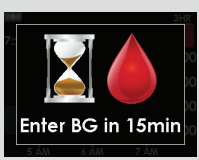
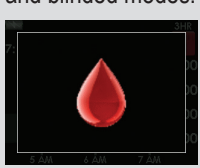
Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
In both real-time and blinded modes: 	Wait 15 minutes calibration error alert	The sensor cannot calibrate. Wait 15 minutes then enter 1 more blood glucose value. Wait 15 more minutes. If error screen still appears enter 1 more blood glucose value. Wait 15 minutes. If no sensor glucose readings appear on the receiver, the sensor needs to be replaced.	Vibrates 1 time and then vibrates/beeps every 5 minutes until confirmed.	No

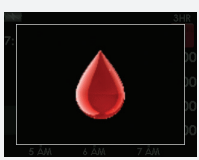
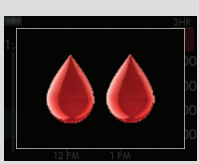
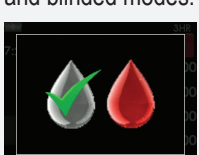
(continued on next page)

Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
In both real-time and blinded modes:	Wait 1 hour calibration error alert	The sensor cannot calibrate. Wait a minimum of 1 hour then enter 1 more blood glucose value for calibration. If no sensor glucose readings appear on the receiver, the sensor needs to be replaced.	Vibrates 1 time and then vibrates/beeps every 5 minutes until confirmed.	No
In both real-time and blinded modes: 	12 hour calibration prompt	The receiver needs a blood glucose value entered to calibrate.	Prompt screen only.	Yes, every 15 minutes.

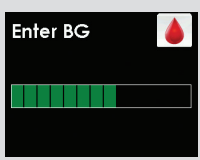
(continued on next page)

Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
In both real-time and blinded modes: 	Calibration prompt	The receiver needs a blood glucose value entered to calibrate. Sensor glucose readings will not be displayed at this time.	Vibrates 1 time then vibrates/beeps every 5 minutes until confirmed.	Yes, every 15 minutes.
In both real-time and blinded modes: 	Startup calibration prompt	The receiver needs 2 blood glucose values entered to calibrate.	Vibrates 1 time and then vibrates/beeps every 5 minutes until confirmed.	Yes, every 15 minutes.
In both real-time and blinded modes: 	Additional startup calibration prompt	The receiver needs 1 additional blood glucose value to complete startup calibration.	Vibrates 1 time and then vibrates/beeps every 5 minutes until confirmed.	Yes, every 15 minutes.

(continued on next page)

Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
In both real-time and blinded modes: 	Enter BG processing screen prompt	The receiver is processing the blood glucose value you entered.	Prompt screen only.	N/A
In real-time mode:	Rise alert	The glucose levels are rising at 2 mg/dL per minute or more.	Vibrates 2 times and then vibrates/beeps 2 times every 5 minutes or until confirmed (2 repeats max).	No
In blinded mode: No display	Disabled	N/A	Disabled	Disabled

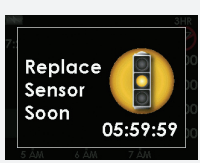
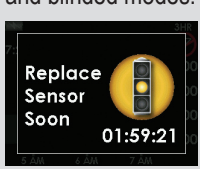
(continued on next page)

Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
In real-time mode: In blinded mode: No display	Rapid rise alert Disabled	The glucose levels are rising fast at 3 mg/dL per minute or more. N/A	Vibrates 2 times and then vibrates/beeps 2 times every 5 minutes or until confirmed (2 repeats max). Disabled	No Disabled
In real-time mode: In blinded mode: No display	Fall alert Disabled	The glucose levels are falling at 2 mg/dL per minute or more. N/A	Vibrates 3 times and then vibrates/beeps 3 times every 5 minutes or until confirmed (2 repeats max). Disabled	No Disabled

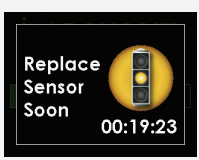
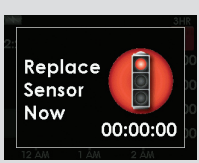
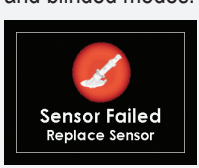
(continued on next page)

Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
In real-time mode: In blinded mode: No display	Rapid fall alert Disabled	The glucose levels are falling fast at 3 mg/dL per minute or more. N/A	Vibrates 3 times and then vibrates/beeps 3 times every 5 minutes or until confirmed (2 repeats max). Disabled	No Disabled
In both real-time and blinded modes:  	6-hour sensor expiration prompt	The sensor session will end in 6 hours.	Prompt screen only.	N/A
In both real-time and blinded modes:  	2-hour sensor expiration alert	The sensor session will end in 2 hours.	Prompt screen only.	No

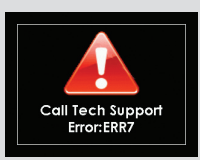
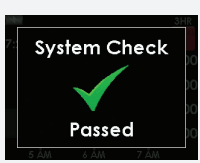
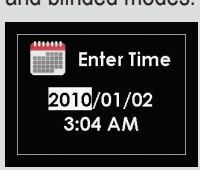
(continued on next page)

Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
In both real-time and blinded modes: 	30-minute sensor expiration alert	The sensor session will end in 30 minutes.	Vibrates 1 time and then vibrates/beeps every 5 minutes (2 repeats max).	No
In both real-time and blinded modes: 	End of session sensor expiration alert	The sensor session has ended.	Vibrates 1 time and then vibrates/beeps every 5 minutes (2 repeats max).	No
In both real-time and blinded modes: 	Sensor failed alert	The sensor is not working properly.	Vibrates 1 time and then vibrates/beeps every 5 minutes (2 repeats max).	Yes, 2 re-alerts in the next 10 minutes for 30 minutes.

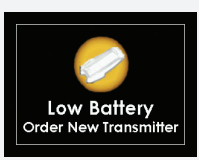
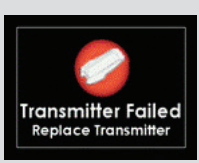
(continued on next page)

Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
In both real-time and blinded modes: 	Receiver error code alert	The receiver is not working properly. Record the error code and call Dexcom Technical Support.	Vibrates 1 time (4 seconds) + 4 beeps.	No
In both real-time and blinded modes: 	System recovery check alert	There was a system error and the receiver fixed it.	Vibrates 1 time and then vibrates/beeps every 5 minutes until confirmed.	No
In both real-time and blinded modes: 	Set time/date prompt	Backup battery has drained, time/date need to be reset.	Vibrates 1 time.	No

(continued on next page)

Receiver Alerts, Alarm and Prompts (continued from page before)

What will I see on the receiver screen?	Prompt, alert or alarm?	What does this mean?	How will the receiver notify me? (vibrate and/or beep)	Will the receiver re-notify me?
In both real-time and blinded modes: 	Transmitter low battery alert	Transmitter battery is low. Replace the transmitter as soon as possible.	Vibrates 1 time and then vibrates/beeps every 5 minutes (2 repeats max).	Yes, once a day.
In both real-time and blinded modes: 	Transmitter failed alert	The transmitter has failed. Replace the transmitter immediately.	Vibrates 1 time and then vibrates/beeps every 5 minutes (2 repeats max).	No

Important alerts that can be checked by the user in both real-time and blinded modes:

- **Out of range alert** - You can test this alert by moving the receiver more than 20 feet away for 30 minutes or more.
- **30-minute sensor expiration alert** - You will see this alert in the normal course of using a sensor for seven days.
- **0-hour sensor expiration alert** - You will see this alert in the normal course of using a sensor for seven days.

Other alerts and alarms cannot be safely checked by the user.

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APPENDIX III, SYMBOLS USED IN LABELING

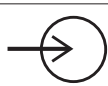
The following symbols may be found on the sensor, transmitter, and receiver package labels. These symbols tell you about the proper and safe use of the Dexcom G4 PLATINUM Professional CGM System. Some of these symbols may not have meaning in your region, and are listed for informational purposes only. This table shows what each symbol means.

Symbols

	"Use By" Date	LOT	Lot Number
	Caution	REF	Part Number, Catalog Number
	Date of Manufacture	STERILE R	Sterile by Radiation
	Do Not Reuse		Two-sided Temperature Limits
SN	Serial Number	IP28	Temporary submersion
	Class II Equipment	IP22	Vertically falling drops
~	Alternating Current	⎓	Direct Current
	Type BF Applied Part		Follow Operating Instructions

(continued on next page)

Symbols (continued from page before)

	Manufacturer		Authorized Representative in the European Community
	Two-Sided Humidity Limitation		Non-Ionizing Radiation
	European Union WEEE Directive 2006-66-EC		Marking Certifies that the Device Meets the European Council Directive 93/42/EEC
	Electrical Equipment Designed Primarily for Indoor Use		Do Not Use if Package is Damaged
	Input	**SB**	Ship By Date
	Keep Dry	**Rx Only**	Prescription Required
	Not Made with Natural Rubber Latex		MR Unsafe

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